COGNITIVE REMEDIATION AND SOCIAL RECOVERY IN EARLY PSYCHOSIS

(THE CReSt-R STUDY)

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BSc., MSc.

Thesis submitted to University of Galway in fulfilment of the requirements for the Degree of Doctor of Philosophy (Psychology)

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Submitted December 2022

“Hope” is the thing with feathers -
That perches in the soul -
And sings the tune without the words -
And never stops - at all –

Emily Dickinson

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Declaration

I declare this thesis has not been submitted as an exercise at this or any other university. I declare this thesis is entirely my own work.

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Emma Frawley

Statement of Contribution

This thesis includes studies involving multiple co-authors. The candidate was actively involved in the design, data collection, analysis, and write-up of each study. The contributions of each co-author on two published articles and one submitted article are described below. The primary supervisor and Graduate Research Committee provided support in conducting the research. The principal investigator, Prof. Gary Donohoe, was designated as corresponding author on all publications as per lab protocol.

Study 1: Social and occupational recovery in early psychosis: a systematic review and meta-analysis of psychosocial interventions - Emma Frawley, Megan Cowman, Martin Lepage and Gary Donohoe. EF was responsible for the study design which was developed through discussions with GD and ML. EF led on the initial electronic search with cross-checks by MC and GD. EF, MC and GD extracted data independently and discrepancies were resolved by consensus. MC contributed to data-analysis and write-up of same. All authors reviewed, edited, and approved the manuscript for publication.

Study 2: Cognitive Remediation and Social Recovery in Early Psychosis (CReSt-R): protocol for a pilot randomised controlled study – Emma Frawley, Megan Cowman, Matteo Cella, Eoin Ryan, Dermot Cohen, Brian Hallahan, Christopher Bowie, Colm McDonald, David Fowler, Til Wykes, Gary Donohoe. EF and GD originated the conception and design of the study. EF led the trial and completed the analysis and interpretation of data with involvement from GD also. MC was the research assistant on the CReSt-R study, completing baseline and follow-up outcome measure assessments. EF completed the intervention protocol with all participants. EF led on the write-up of the protocol in addition to the trial registration. All authors reviewed and approved the manuscript for publication.

Study 4: Young people perspectives in cognitive remediation and social recovery in early psychosis (CReSt-R): an acceptability study – Emma Frawley, Caroline Heary, Clio Berry, Matteo Cella, David Fowler, Til Wykes, Gary Donohoe. EF led on the study design, data analysis and write-up. GD completed the semi-structured interviews (EF was the primary

treating therapist). CH and CB contributed to data analysis as described in the manuscript. All authors reviewed and approved the manuscript for publication.

Funding

This research was funded by the Irish Health Research Board (HRB) as part of the Collaborative Doctoral Award Program in Youth Mental Health Leadership (YOULEAD).

(HRB grant number: CDA-2018-001).

I would like to sincerely thank the HRB for the Clinical Fellowship award and the support over the four years of the program.

Acknowledgements

Firstly, I would like to express my sincere gratitude to my supervisor, Prof. Gary Donohoe, for his support, guidance, and spirit of generosity throughout the PhD process. His mentorship, patience and encouragement have been instrumental in my ability to reach the point of thesis submission. Thank you for your dedicated time and supporting my development from clinician to clinical academic while tackling imposter syndrome flare-ups along the way. It has been my pleasure working with you over the last four years.

I would also like to thank Megan Cowman for her work as research assistant and co-author contribution on the CReSt-R study. Her boundless energy and enthusiasm are something to behold, and I wish her the very best of luck on her own PhD journey. Thank you also to Dr Caroline Heary and Dr Clio Berry for their support and guidance in completing the qualitative research work in this thesis. I thoroughly enjoyed the process and look forward to delving into the qualitative research world again in the future.

I am grateful to have had the opportunity to collaborate with internationally renowned experts. Thank you to Prof. Til Wykes, Dr Matteo Cella, Prof. David Fowler, Prof. Christopher Bowie, and Prof. Martin Lepage for their input and constructive feedback on this doctoral research.

I am also thankful for the Youlead research group, both principal investigators and trainees. I am proud of the collective body of work we have achieved over the last four years. A special thank you to Olive O'Grady and Emer Conneely for the chats, cups of tea, laughs and support in the first year of the program when I was still wondering what on earth I had gotten myself into. I would also like to thank my friends and colleagues from the CogGene and NICOG research groups. Thank you also to my graduate research committee, Prof. AnnMarie Groarke, Dr Ian Stewart, and Dr Aoife McTiernan, for their support and encouragement.

I would like to express my deepest gratitude to the young people who took part in the CReSt-R study and YAP. This endeavour would not have been possible without you. I enjoy getting updates on how you are doing and wish you all the best in the future.

On a personal note, thank you to my friend group for the support and grounding throughout the PhD process. There are too many in the tribe to mention but you know who you are (also, you will never read this).

Words cannot express my gratitude to my parents, Brian and Marie. Thank you for all your love, encouragement, and support from day dot. Your selflessness and hard work over the years ensured my sisters and I could seize every opportunity that came our way and has been instrumental in where we all are today. Thank you to my sisters, Nicola and Vanessa, and brother-in-law, Joe for always being there for me. I always feel your support and encouragement in anything that I do - the best cheerleading squad ever. A special mention to my two beautiful nieces, Melanie and Hayley, who arrived into the world during my PhD journey. You are an infinite source of joy for the entire family.

Finally, and above all, thank you to my wonderful husband Craig. Your unwavering belief in me kept me going through the highs and lows of this experience. Thank you for always helping to keep things in perspective, for continuing to make me laugh, and being the best cook in the house. Your love and support have encouraged me to reach the finish line and I dedicate this thesis to you.

About the structure of this thesis

This thesis is presented as a PhD by publication. Chapter 2 and 3 are pre-print copies of published journal articles. They, along with study supplementary materials, can also be accessed on the journal websites via the hyperlinks contained within each chapter. Chapter 5 is presented as a manuscript currently submitted for publication and under review. Chapter 4, along with the general introduction and discussion were written specifically for this thesis. For consistency and ease of readability each chapter has its own reference list.

Abstract

Background Psychosis, even in its early stages, is associated with significant disability, causing it to be ranked ahead of paraplegia and blindness in those aged 18–35 in terms of years lived with disability. Current pharmacological and psychological interventions have focused primarily on the reduction of positive symptoms (hallucinations and delusions), with little benefit to domains of psychosis such as cognitive difficulties and social and occupational functioning. The overall aim of this doctoral research was to further explore and develop the evidence base for psychosocial intervention in early psychosis with a particular emphasis on social and occupational function and social cognition as outcomes of interest.

Methods The overall aim of this research was achieved by addressing a number of key objectives: 1) Completion of a systematic review of the literature to collate current empirical evidence for the impact of psychosocial intervention on functional outcomes in the at-risk and early psychosis cohorts. An electronic search was conducted using PubMed and PsycINFO to identify original articles reporting on trials of psychosocial interventions in early-stage psychosis, published up to December 2020 and is reported following PRISMA guidelines. Data were extracted on validated measures of functioning from included studies and pooled standardised mean difference (SMD) was estimated (chapter 2).

2) Development of a protocol for a multi-component intervention which targets both cognitive and functional domains in early psychosis (Cognitive Remediation and Social Recovery in Early Psychosis (CReSt-R). Protocol development was informed by the Medical Research Council framework for developing and evaluating complex interventions (chapter 3).

3) Completion of a randomised pilot study of this novel, multi-component CReSt-R intervention in the early psychosis cohort. This study reports on a number of feasibility indicators, progression criteria, and exploratory statistical analysis using a linear mixed model and descriptive statistics (chapter 4).

4) Completion of an acceptability study of the CReSt-R intervention to young people living with psychosis. This study employed a qualitative research design, based on semi-structured interviews and reflexive thematic analysis (chapter 5).

Results Study one, a systematic review and meta-analysis, reported improved function across interventions, (SMD = 0.239; 95% confidence interval 0.115–0.364, $p < 0.001$). Effect sizes varied by intervention type, stage of illness, length and duration of treatment, treatment setting, and outcome measure used. In particular, interventions based on CRT significantly outperformed symptom-focused CBT interventions, while multi-component interventions were associated with largest gains.

Study two presents the research protocol for the Cognitive Remediation and Social Recovery in Early Psychosis (CReSt-R) study. This publication is a culmination of in-depth research on existing cognitive remediation training and psychosocial therapies, trial methodologies, and collaboration with international experts which led to the development of the protocol.

Study three reports that the CReSt-R intervention met feasibility and progression criteria, Exploratory linear mixed-effects model (LMM) analysis demonstrated that both control and intervention groups were found to improve on a number of social and occupational functioning, social cognitive and symptom outcome measures over the duration of the study and follow-up time points. However, there was no significant difference observed between the control and intervention group across outcome measures.

Study four describes four themes developed through the analytical process of a qualitative study, namely, (1) a solid therapeutic foundation, (2) multi-directional flow of knowledge, (3) a tailored toolset, and (4) an individual pathway to recovery. Participants also provided pragmatic feedback about how to improve the delivery of the therapy intervention. Both the themes and pragmatic feedback are described.

Conclusion Cognition is an important (and often overlooked) intervention target in early intervention in psychosis. Multi-component interventions appear to have the greatest impact on functional outcomes. New evidence emerging from this thesis highlights the effectiveness of psychosocial intervention on social and occupational function while reporting on methodological limitations and recommendations for optimising future research study design. New feasibility and acceptability data of a novel psychosocial intervention is also reported, providing a platform for further development of the intervention. Consensus studies of the definition of clinical recovery, measures of social and occupational functioning with the inclusion of public patient involvement at the core, is a recommendation for future research

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Chapter 2

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List of Abbreviations

AMHS	Adult Mental Health Service
BLERT	Bell Lysaker Emotion Recognition Task
Brief-A	Behaviour Rating Inventory of Executive Function
CAMHS	Child and Adolescent Mental Health Service
CBTp	Cognitive Behavioural Therapy for Psychosis
CIRCuiTS	Computerised Interactive Remediation of Cognition-Training for Schizophrenia
CI	Confidence Interval
CMA	Comprehensive Meta-Analysis Software
CReSt-R	Cognitive Remediation and Social Recovery in Early Psychosis Study
CREW	Cognitive Remediation Experts Workshop
CRT	Cognitive Remediation Training
DUP	Duration of untreated psychosis
EIP	Early Intervention in Psychosis
EIS	Early Intervention for Psychosis Services
ERT	Emotion Recognition Task
FBT	Family-based Therapy
FEP	First-episode Psychosis
FIQ	Full-scale Intelligence Quotient
GAF	Global Assessment of Functioning Scale
GFR	Global Functioning Role Scale
GFS	Global Functioning Scale
HRB	Health Research Board
IMI	Intrinsic Motivation Inventory
IPS	Individual Placement Support
LMM	Linear Mixed-effects Model
LSP-39	Life Skills Profile

MAP-SR	Motivation and Pleasure-Self Report scale
MRC	Medical Research Council
NCS	The Need for Cognition Scale
NICE	National Institute for Health and Care Excellence
NICOG	Centre for Neuroimaging, Cognition & Genomics
OSA	Occupational Self-Assessment
PANSS	Positive and Negative Syndrome Scale
PSP	Personal Social Performance Scale
PPI	Public Patient Involvement
RCT	Randomised Controlled Trial
RFS	Role Functioning Scale
ROCF	Rey Osterreith Complex Figure
SAS	Social Adjustment Scale
SBS	Social Behaviour Schedule
SCOPE	Social Cognition Psychometric Evaluation Study
SD	Standard Deviation
SFS	Social Functioning Scale
SIAS	Social Interaction Anxiety Scale
SIPS	Structured Interview for Psychosis-Risk Syndromes
SMD	Standardised Mean Difference
SOFAS	Social and Occupational Functioning Assessment Scale
SRT	Social Recovery Therapy
SSPA	Social Skills Performance Assessment
SZ	Schizophrenia
TAU	Treatment As Usual
TUS	Time Use Survey
TUS (CEA)	Time Use Survey (constructive economic activity)
TUS (SA)	Time Use Survey (structured activity)
UHR	Ultra High Risk
UPSA-B	UCSD Performance-Based Skills Assessment
WHO	World Health Organisation
WAIS-III	Wechsler Adult Intelligence Scale 3rd Edition
WMS-111	Wechsler Memory Scale, 3rd Edition
YAP	Youth Advisory Panel

Chapter 1. Introduction

1.1 The context for early intervention in psychosis

The Early Intervention in Psychosis (EIP) model of care began to emerge almost three decades ago with countries including Australia, Canada and the United Kingdom adopting this approach. In its infancy, this model was not without controversy. Opponents questioned its cost-effectiveness, and the lack of evidence of the long-term benefits of investing in such a model of care - even going as far as to state that dogma was being placed before facts (Bosanac et al., 2010; Pelosi V Birchwood, 2003). Proponents of the model also constructively questioned the maintenance and longevity of clinical and functional gains once the individual returned to a generic mental health service and the utility and complexity of including those individuals at risk for psychosis (McGorry, 2005;Singh, 2010).

More recently, Correll et al. (2018), building upon the only previous meta-analysis of EIP by Bird et al. (2010), compared early intervention services versus treatment as usual for early-phase psychosis. Including 10 trials in the analysis, superior clinically important outcomes were observed in the first two years of EIP over treatment as usual. This meta-analysis represents a pivotal study in building the evidence base for EIP services, propelling the discussion beyond whether EIP works but rather how it works and the active ingredients of effective intervention in this cohort. It also places a focus on implementation of research into practice and clinical guidelines (McGorry et al., 2018).

A fundamental aim of EIP services has been to reduce the duration of untreated psychosis (DUP), informed by a clinical staging model (McGorry et al., 2007). Evidence suggests that a longer DUP has a detrimental effect on individual outcomes i.e. level of social and occupational function, response to appropriate treatment and quality of life (Perkins et al.,2005; Melle et al., 2006).This is based on the critical period hypothesis that in the first two-three years of psychosis (including the prodromal phase) long-term outcome is predictable and biological, psychological and psychosocial influences show greatest potential for change (Birchwood et al., 1998). The clinical staging model places an individual on a continuum of severity and chronicity, ranging from stage 0 (at risk but asymptomatic) to stage 4 (chronic and unremitting) (Fava & Kellner,1993;McGorry et al., 2007). This approach enables assessment and treatment intensity to match the individual's clinical need with the potential to have the greatest impact on prevention, engagement with service,

recovery, and trajectory of the disorder (Byrne & Rosen, 2014; McGorry et al., 2007). Stages of psychosis are described in the literature as 1) at-risk or ultra-high-risk (UHR) 2) first-episode psychosis (FEP) 3) early psychosis (within the first five years of a diagnosed psychotic disorder and 4) chronic psychosis (Fusar-Poli 2013; McGorry et al., 2018). The research in this thesis focuses primarily on first episode and early psychosis, with the exception of the systematic review and meta-analysis presented in chapter two which includes the at-risk cohort.

Adopting a clinical staging model to psychosis spectrum disorders, demonstrated to be an effective approach in physical disease, also comes with caveats. It has been suggested the clinical staging model does not account for the multifaceted etiology of psychosis, which includes a complex interaction of the individual with their environment and resulting in complex co-morbidities, as evidenced by epidemiological studies of development of the disorder across the lifespan (Gupta & Mittal, 2019; Kuipers, 2008; McGorry, 2015). This includes the role of adverse childhood experiences (including childhood traumas such as neglect and abuse) in the later development of adult mental health disorders (Read et al., 2014). Advances in neuroscience research demonstrate changes at a brain level after exposure to childhood trauma, including an over-reactive amygdala which translates functionally to a disproportionate response to perceived threat (Mothersill & Donohoe, 2016). Exposure to adverse childhood events also correlates to deficits in social cognition (Rokita et al., 2018) with exposure to physical neglect being the strongest predictor of social cognitive deficits (Rokita et al., 2020). This is an important consideration in the individual etiology and functional trajectory (recovery) of an individual with psychosis, and also in the research, design, implementation and evaluation of intervention and services in this area.

1.2 Cognition, social and occupational function, and psychosis

Cognitive deficits as predictors of functional recovery in psychosis are widely reported in the literature (Allot et al., 2011; Fett et al., 2011; Santesteban et al., 2017; Cowman et al., 2021). Impairment in both neurocognition and social cognition are present across all stages of psychosis from the at-risk, FEP and early psychosis cohorts (Aas et al., 2014; Green et al., 2019; Halverson et al., 2019), and persist in chronic cases of psychosis, such as schizophrenia (Lepage et al., 2014). This reflects enduring impairments in both neurocognition and social cognition, that are not addressed by pharmacological intervention, and that continue to have a

significant impact on social and occupational function and the rate of disability in those living with psychosis (Fett et al., 2011, Horan & Green, 2019).

Across psychosis spectrum disorders, social cognition in particular, is strongly linked to functional outcomes and therefore considered an important target for intervention (Bora et al., 2009; Horan et al., 2009; Kurtz et al., 2012; Pinkham et al., 2013; Cowman et al., 2021). Social Cognition is reported to mediate the effects of neurocognition on functional outcomes (Addington et al., 2006; Green & Horan, 2010, Fett et al., 2011), leading to the suggestion that better functional outcomes may be achieved if both neurocognition and social cognition are targeted in interventions (Green & Horan, 2010). Importantly, these deficits are observed to remain even when clinical symptoms have been successfully treated (Cowman et al, 2021).

Social cognitive deficits impact on normative life roles throughout the lifespan. Normative life roles and community integration include activities of daily living, instrumental activities of daily living, social participation, leisure, work, and education (Gibson et al., 2011). Polatajko et al. (2007) summarise these activities into three key areas: self-care, productivity, and leisure. The ability of an individual to meaningfully participate in these activities may be undermined by social cognitive impairment, social withdrawal, and the experience of positive and negative symptoms in psychosis.

People living with experience of psychosis often experience barriers to socialising. For example, experience of positive symptoms (e.g. hallucinations) can result in psychological challenges and reduced opportunities to meet and engage with other individuals in a social context (Joseph et al., 2017, Sheridan et al., 2014). This compounds social avoidant behaviours, cognitive deficits and resulting disability. In a review of social cognitive interventions, Fiszdon et al., (2012) conclude that in order to impact higher-order social cognitive processes, there needs to be ample opportunity for practice of skills both in a clinical setting as well as in the community.

1.3 The recovery framework

While cognition thus far has been framed in the context of deficits and impairment, it is not the intention of the author to be pessimistic, but rather to highlight cognition as an important (and often ignored) target for intervention in early psychosis with the potential to improve functional outcomes and to promote hope in this context. The recovery model is integral to

EIP services. Evidence suggests both remission and recovery after a first episode of psychosis are possible (Davidson et al., 2005; Lally et al., 2017; Asbo et al., 2022). Remission refers to symptomatic and/or functional improvement over a >6-month time frame and using specific assessment criteria (The Remission in Schizophrenia Working Group RSWG criteria).

Recovery refers to a multidimensional concept which encompasses symptomatic remission and functional improvement in social, occupational, and educational domains over a time frame of >2 years (Lally et al., 2017). In their meta-analysis of long-term outcome studies of FEP, Lally et al. found that 58% of participants met remission criteria at a mean of 5 years and 38% met recovery criteria at a mean of 7.2 years.

A critique of the recovery ethos in current mental health services, including EIP services, is the perceived dominance of the biomedical model. Service user groups describe appropriation of the term by mental health professionals and policy makers as an outcome of service provision e.g. to justify funding. McCabe et al. (2018) present the perspectives of mental health service users who conceptualise recovery as a dynamic process, a lived experience in addition to an outcome. They also highlight the risk of service users internalising professional and service definition or understanding of recovery and the ethical implications of same. This highlights the importance of public patient involvement (PPI) in the research process in addition to prioritising research of acceptability of interventions to people living with psychosis (Norton and McLaughlin, 2022; Vita et al., 2022).

1.4 Interventions targeting social function and cognition in psychosis

Research and development of psychosocial interventions which target neurocognition and social cognition has evolved with cognitive remediation training (CRT) at the fore of this research. CRT is a 'behavioural training-based intervention which aims to improve cognitive processes (attention, memory, executive function, social cognition or metacognition) with the goal of durability and generalisation' (Cognitive remediation working group, 2012). A landmark meta-analysis of CRT reported, despite variability in methodological rigour, significant benefits for cognition (d= 0.45), psychosocial functioning (d= 0.42) and symptoms (d= 0.18) (Wykes et al., 2011). It also concluded that CRT is most effective when provided together with adjunctive rehabilitation. A more recent meta-analysis continued to demonstrate that CRT was effective in improving cognition (d= 0.29) and functioning (d=

0.22) while also identifying key ingredients predicting efficacy that included an active and trained therapist, and structured delivery of cognitive strategies, practice of which is integrated with psychosocial rehabilitation (Vita et al., 2021).

To date, interventions targeting social cognition have been targeted at a specific domain of social cognition such as emotion processing or facial affect recognition. A meta-analytic investigation of social cognitive training for schizophrenia in 2012 reported moderate-large effects of social cognitive training procedures specifically on facial affect recognition (d= 0.71, small-moderate effects on mentalising (d= 0.48) and moderate –large effects on observer-rated community and institutional function (d= 0.78) (Kurtz et al., 2012).These results should be interpreted with caution when considering generalisability to young people living with psychosis in the community however, as a large proportion of the included studies were based in in-patient settings in addition to a noted heterogeneity of outcome measures utilised particularly with regard to social functioning.

Psychosocial interventions (including CRT) that target social cognition specifically have varied in methodology and shown inconsistent evidence of generalisation to real-world functioning (Horan & Green, 2019, Kurtz et al., 2016, Kurtz et al., 2012). Horan & Green (2019) further expand on the current status of social cognitive interventions stating there is a need to develop novel, methodologically rigorous psychosocial interventions which target multiple social cognitive domains, and which demonstrate an increased level of generalisability to community functioning.

Other psychosocial interventions included in current clinical guidelines focus on the provision of pharmacological intervention in conjunction with several specific psychosocial interventions (namely, cognitive behavioural therapy for psychosis (CBTp), family-based interventions and supported employment) (National Institute for Health and Care Excellence (NICE), 2014,2015). There is an identified need for continued development of psychosocial intervention that target neurocognition, social cognition and function in psychosis spectrum disorders and contribute to the empirical evidence for (a) the benefit of psychosocial intervention in this population and (b) that identifies the active ingredients of such interventions.

1.5 Complex interventions

Design, implementation, and evaluation of intervention in early psychosis is as complex as the etiology and heterogeneity of presentations in this cohort. An intervention may be considered complex based on the number of components involved, the intervention targets, the skills required by the therapist and patient, the setting, the flexibility of the intervention protocol, and the interaction of the intervention and its context (Skivington et al.,2021). While randomised control trials remain the gold standard for evidence of efficacy of an intervention, it is important to consider the optimal trial design to address other important factors such as feasibility, acceptability, and effectiveness (i.e. 'real world' performance). This research is guided by the Medical Research Council (MRC) framework for evaluating complex interventions (Craig et al., 2008; Skivington et al., 2021).

1.6 Gaps in the research on cognition, social function, and early psychosis.

A number of key gaps in our knowledge about psychosocial interventions that target cognitive and social/occupational function remain in the literature and are the focus of the work in this thesis.

These include:

1. What is the evidence that cognitive and psychosocial function is improved by existing psychosocial interventions?
2. Is it feasible to combine cognitive remediation and cognitive behavioural therapy? Would this be acceptable to those receiving the intervention?
3. What is the evidence that combining CRT and CBT would lead to improved outcomes for individuals in the early stages of psychosis?

1.7 Research aims of this thesis

The overall aim of this doctoral research was to further explore and develop the evidence base for psychosocial intervention in early psychosis with a particular emphasis on social and

occupational function and social cognition as outcomes of interest. This aim was achieved through a number of key objectives:

1) Completion of a systematic review of the literature to collate current empirical evidence for the impact of psychosocial intervention on functional outcomes in the at-risk and early psychosis cohorts (chapter 2).
2) Development of a protocol for a multi-component intervention which targets both cognitive and functional domains in early psychosis (Cognitive Remediation and Social Recovery in Early Psychosis (CReSt-R) (chapter 3).
3) Completion of a randomised pilot study of this novel, multi-component CReSt-R intervention in the early psychosis cohort (chapter 4).
4) Completion of an acceptability study of the CReSt-R intervention to young people living with psychosis (chapter 5).

1.8 The context for the work presented in this thesis

The research carried out in this thesis was carried in the context of a doctoral fellowship as part of a Health Research Board collaborative doctoral award entitled 'YOULEAD', a doctoral training program in Youth Mental Health Research. The program represented a collaboration between academic researchers, clinical researchers, health service providers, and other stakeholders. A key objective of the program was to train future leaders in youth mental health by enabling clinicians working in the health services to complete doctoral training.

The YOULEAD consortium included members from the University of Galway, University College Dublin, and the Royal College of Surgeon's in Ireland, and clinicians from the Health Service Executive and JIGSAW, the national service for youth mental health. The studies provided in the thesis were carried out in collaboration with the Galway University hospital adult mental health services, which serves a catchment area of ~250,000 individuals. There were three research pillars for the program: 1. To identify preventable risk factors for youth mental health; 2. To overcome the barriers to accessing treatment, and 3) To evaluate existing treatments and build on these with novel programs. This thesis was carried out under pillar 3.

1.9 References

Aas, M., Dazzan, P., Mondelli, V., Melle, I., Murray, R. M., & Pariante, C. M. (2014). A systematic review of cognitive function in first-episode psychosis, including a discussion on childhood trauma, stress, and inflammation. *Frontiers in Psychiatry*, 4. doi:10.3389/fpsyt.2013.00182

Addington, J., Saeedi, H., & Addington, D. (2006). Facial affect recognition: a mediator between cognitive and social functioning in psychosis?. *Schizophrenia research*, *85*(1-3), 142–150. https://doi.org/10.1016/j.schres.2006.03.028

Allott, K., Liu, P., Proffitt, T. M., & Killackey, E. (2011). Cognition at illness onset as a predictor of later functional outcome in early psychosis: systematic review and methodological critique. *Schizophrenia research*, *125*(2-3), 221–235. https://doi.org/10.1016/j.schres.2010.11.001

Åsbø, G., Ueland, T., Haatveit, B., Bjella, T., Flaaten, C. B., Wold, K. F., Widing, L., Engen, M. J., Lyngstad, S. H., Gardsjord, E., Romm, K. L., Melle, I., & Simonsen, C. (2022). The Time is Ripe for a Consensus Definition of Clinical Recovery in First-episode Psychosis: Suggestions Based on a 10-Year Follow-up Study. *Schizophrenia bulletin*, *48*(4), 839–849. https://doi.org/10.1093/schbul/sbac035

Birchwood, Max & Todd, Pauline & Jackson, Christopher. (1998). Early intervention in psychosis: The critical period hypothesis. *British Journal of Psychiatry*. 172. 53-59. 10.1192/S0007125000297663.

Bird, V., Premkumar, P., Kendall, T., Whittington, C., Mitchell, J., & Kuipers, E. (2010). Early intervention services, cognitive-behavioural therapy and family intervention in early psychosis: systematic review. *British journal of Psychiatry*, *197*(5), 350-356. doi:10.1192/bjp.bp.109.074526

Bora, E., Yucel, M., Pantelis, C. (2009) Theory of mind impairment in schizophrenia: metaanalysis. Schizophr. Res., 109, 1-9.

Bosanac, P., Patton, G. C., & Castle, D. J. (2010). Early intervention in psychotic disorders: faith before facts?. *Psychological medicine*, *40*(3), 353–358. https://doi.org/10.1017/s0033291709990341

Byrne, P., & Rosen, A. ed. (2014). Early Intervention in Psychiatry: EI of Nearly Everything for Better Mental Health. Wiley Blackwell: Oxford, UK.

Correll, C., Galling, B., Pawar, A., Krivko, A., Bonetto, C., & Ruggeri, M. et al. (2018). Comparison of Early Intervention Services vs Treatment as Usual for Early-Phase Psychosis. *JAMA Psychiatry*, *75*(6), 555. doi: 10.1001/jamapsychiatry.2018.0623

Cowman, M., Holleran, L., Lonergan, E., O'Connor, K., Birchwood, M., & Donohoe, G. (2021). Cognitive Predictors of Social and Occupational Functioning in Early Psychosis: A Systematic Review and Meta-analysis of Cross-Sectional and Longitudinal Data. *Schizophrenia bulletin*, *47*(5), 1243–1253. https://doi.org/10.1093/schbul/sbab033

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., Petticrew, M., & Medical Research Council Guidance. (2008). Developing and evaluating complex interventions: the

new Medical Research Council guidance. *British Medical Journal (Clinical research ed.), 337*, a1655. https://doi.org/10.1136/bmj.a1655

Davidson, L., Borg, M., Mann, I., Topor, A., Mezzina, R., & Sells, D. (2005). Processes of Recovery in Serious Mental Illness: Findings from a Multinational Study. *American Journal of Psychiatric Rehabilitation, 8*(3), 177–201. https://doi.org/10.1080/15487760500339360

Fava, G. A., & Kellner, R. (1993). Staging: a neglected dimension in psychiatric classification. *Acta psychiatrica Scandinavica*, *87*(4), 225–230. https://doi.org/10.1111/j.1600-0447.1993.tb03362.x

Fett, A. K., Viechtbauer,W., Dominguez, M. D., Penn, D. L., van Os, J., & Krabbendam, L. (2011). The relationship between neurocognition and social cognition with functional outcomes in schizophrenia: a meta-analysis. *Neuroscience and biobehavioral reviews*, *35*(3), 573–588. https://doi.org/10.1016/j.neubiorev.2010.07.001

Fiszdon, J. M., & Reddy, L. F. (2012). Review of social cognitive treatments for psychosis. *Clinical psychology review*, *32*(8), 724–740. https://doi.org/10.1016/j.cpr.2012.09.003

Fusar-Poli, P., Borgwardt, S., Bechdolf, A., Addington, J., Riecher-Rössler, A., Schultze-Lutter, F., Keshavan, M., Wood, S., Ruhrmann, S., Seidman, L. J., Valmaggia, L., Cannon, T., Velthorst, E., De Haan, L., Cornblatt, B., Bonoldi, I., Birchwood, M., McGlashan, T., Carpenter, W., McGorry, P., … Yung, A. (2013). The psychosis high-risk state: a comprehensive state-of-the-art review. *JAMA psychiatry*, *70*(1), 107–120. https://doi.org/10.1001/jamapsychiatry.2013.269

Gibson, R., D'Amico, M., Jaffe, L., & Arbesman, M. (2011). Occupational Therapy Interventions for Recovery in the Areas of Community Integration and Normative Life Roles for Adults With Serious Mental Illness: A Systematic Review. *American Journal of Occupational Therapy*, 65(3), 247-256. doi: 10.5014/ajot.2011.001297

Green, M. F., & Horan, W. P. (2010). Social Cognition in Schizophrenia. *Current Directions in Psychological Science*, 19(4), 243–248. https://doi.org/10.1177/0963721410377600

Green, M. (2016). Impact of Cognitive and Social Cognitive Impairment on Functional Outcomes in Patients With Schizophrenia. *The Journal Of Clinical Psychiatry*, 77(Suppl 2), 8-11. doi: 10.4088/jcp.14074su1c.02

Green, M. F., Horan, W. P., & Lee, J. (2019). Nonsocial and social cognition in schizophrenia: current evidence and future directions. *World psychiatry : official journal of the World Psychiatric Association (WPA)*, *18*(2), 146–161. https://doi.org/10.1002/wps.20624

Gupta, T., & Mittal, V. A. (2019). Advances in clinical staging, early intervention, and the prevention of psychosis. *F1000Research*, *8*, F1000 Faculty Rev-2027. https://doi.org/10.12688/f1000research.20346.1

Halverson, T. F., Orleans-Pobee, M., Merritt, C., Sheeran, P., Fett, A. K., & Penn, D. L. (2019). Pathways to functional outcomes in schizophrenia spectrum disorders: Meta-analysis of social cognitive and neurocognitive predictors. *Neuroscience and biobehavioral reviews*, *105*, 212–219. https://doi.org/10.1016/j.neubiorev.2019.07.020

Horan, W., Kern, R., Shokat-Fadai, K., Sergi, M., Wynn, J., & Green, M. (2009). Social cognitive skills training in schizophrenia: An initial efficacy study of stabilized outpatients. *Schizophrenia Research*, 107(1), 47-54. doi: 10.1016/j.schres.2008.09.006

Horan, W., & Green, M. (2019). Treatment of social cognition in schizophrenia: Current status and future directions. *Schizophrenia Research*, 203, 3-11. doi: 10.1016/j.schres.2017.07.013

Joseph, J., Kremen, W., Franz, C., Glatt, S., van de Leemput, J., & Chandler, S. et al. (2017). Predictors of current functioning and functional decline in schizophrenia. *Schizophrenia Research*, 188, 158-164. doi: 10.1016/j.schres.2017.01.038

Kuipers, E. (2008). The case for early, medium and late intervention in psychosis. *World Psychiatry, 7*(3), 158-159. doi:10.1002/j.2051-5545.2008.tb00184.x

Kurtz, M., & Richardson, C. (2012). Social Cognitive Training for Schizophrenia: A MetaAnalytic Investigation of Controlled Research. *Schizophrenia Bulletin*, 38(5), 1092-1104. doi:10.1093/schbul/sbr036

Kurtz, M. M., Gagen, E., Rocha, N. B., Machado, S., & Penn, D. L. (2016). Comprehensive treatments for social cognitive deficits in schizophrenia: A critical review and effect-size analysis of controlled studies. *Clinical psychology review*, *43*, 80–89. https://doi.org/10.1016/j.cpr.2015.09.003

Lally, J., Ajnakina, O., Stubbs, B., Cullinane, M., Murphy, K., Gaughran, F., & Murray, R. (2017). Remission and recovery from first-episode psychosis in adults: A systematic review and meta-analysis of long-term outcome studies. *European Psychiatry, 41*, S819. doi: 10.1016/j.eurpsy.2017.01.1595

Lepage, M., Bodnar, M., & Bowie, C. R. (2014). Neurocognition: clinical and functional outcomes in schizophrenia. *Canadian journal of psychiatry. Revue canadienne de psychiatrie*, *59*(1), 5–12. https://doi.org/10.1177/070674371405900103

McCabe, R., Whittington, R., Cramond, L., & Perkins, E. (2018). Contested understandings of recovery in mental health. *Journal Of Mental Health*, *27*(5), 475-481. doi: 10.1080/09638237.2018.1466037

Mcgorry, P. D. (2005). Early intervention in psychotic disorders: beyond debate to solving problems. *British Journal of Psychiatry*, 187(S48), s108–s110. http://doi.org/10.1192/bjp.187.48.s10

McGorry, P., Ratheesh, A., & O'Donoghue, B. (2018). Early Intervention—An Implementation Challenge for 21st Century Mental Health Care. *JAMA Psychiatry*, *75*(6), 545. doi: 10.1001/jamapsychiatry.2018.0621

McGorry, P. D., Purcell, R., Hickie, I. B., Yung, A. R., Pantelis, C., & Jackson, H. J. (2007). Clinical staging: a heuristic model for psychiatry and youth mental health. *Med J Aust, 187*(S7), S40-42.

McGorry, P. D., E. Killackey, and A. Yung. (2008). Early intervention in psychosis: concepts, evidence and future directions: *World Psychiatry*, v. 7, p. 148-56

McGorry P. D. (2015). Early intervention in psychosis: obvious, effective, overdue. *The Journal of nervous and mental disease*, *203*(5), 310–318. https://doi.org/10.1097/NMD.0000000000000284

Melle, I., Johannesen, J. O., Friis, S., Haahr, U., Joa, I., Larsen, T. K., Opjordsmoen, S., Rund, B. R., Simonsen, E., Vaglum, P. & McGlashan, T. (2006). Early detection of the first episode of schizophrenia and suicidal 248ehaviour. *American Journal of Psychiatry* 163, 800-4.

Mothersill, O., & Donohoe, G. (2016). Neural effects of social environmental stress – an activation likelihood estimation meta-analysis. *Psychological Medicine*, 46(10), 2015–2023. http://doi.org/10.1017/S0033291716000477

National institute for Health and Care Excellence (NICE). (2014). Psychosis and Schizophrenia in Adults: Prevention and Management, National Clinical Practice Guidelines (CG178). Retrieved from https://www.nice. org.uk/guidance/cg178/evidence/full-guideline-490503565.

National institute for Health and Care Excellence (NICE). (2015). Quality Standards for Mental Health Early Intervention Service Provision for Adults with Psychosis or Schizophrenia. Retrieved from https://www.nice. org.uk/guidance/qs80.

Norton, Michael John, and Mia McLaughlin. (2022). "Fusion of Clinical and Lived Experiences of Psychosis: Lessons Learned and Implications for Future Clinical Teaching" *Psychiatry International* 3, no. 4: 286-296. https://doi.org/10.3390/psychiatryint3040023

Pelosi, A. J., & Birchwood, M. (2003). Is early intervention for psychosis a waste of valuable resources? *British Journal of Psychiatry*, 182(3), 196–198. http://doi.org/10.1192/bjp.182.3.196

Perkins, D. O., H. Gu, K. Boteva, and J. A. Lieberman.(2005). Relationship between duration of untreated psychosis and outcome in first-episode schizophrenia: a critical review and meta-analysis: *American Journal of Psychiatry*, v. 162, p. 1785-804

Pinkham, A., Penn, D., Green, M., Buck, B., Healey, K., & Harvey, P. (2013). The Social Cognition Psychometric Evaluation Study: Results of the Expert Survey and RAND Panel. *Schizophrenia Bulletin*, 40(4), 813-823. doi: 10.1093/schbul/sbt081

Polatajko, H.J., Townsend, E.A. & Craik, J. (2007). Canadian Model of Occupational Performance and Engagement (CMOP-E). In Enabling Occupation II: Advancing an Occupational Therapy Vision of Health, Well-being, & Justice through Occupation. E.A. Townsend & H.J. Polatajko, Eds. Ottawa, ON: CAOT Publications ACE. 22-36

Read, J., Fosse, Roar, Moskowitz, Andrew and Perry, Bruce. (2014). The traumagenic neurodevelopmental model of psychosis revisited. *Neuropsychiatry*. 4 (1), pp. 65-79. https://doi.org/10.2217/NPY.13.89

Rokita, K. I., Dauvermann, M. R., & Donohoe, G. (2018). Early life experiences and social cognition in major psychiatric disorders: A systematic review. *European Psychiatry*, 53, 123–133. http://doi.org/10.1016/j.eurpsy.2018.06.006

Rokita, K. I., Holleran, L., Dauvermann, M. R., Mothersill, D., Holland, J., Costello, L., Kane, R., McKernan, D., Morris, D. W., Kelly, J. P., Corvin, A., Hallahan, B., McDonald, C., & Donohoe, G. (2020). Childhood trauma, brain structure and emotion recognition in patients

with schizophrenia and healthy participants. *Social cognitive and affective neuroscience*, *15*(12), 1336–1350. https://doi.org/10.1093/scan/nsaa160

Santesteban-Echarri, O., Paino, M., Rice, S., González-Blanch, C., McGorry, P., Gleeson, J., & Alvarez-Jimenez, M. (2017). Predictors of functional recovery in first-episode psychosis: A systematic review and meta-analysis of longitudinal studies. *Clinical psychology review*, *58*, 59–75. https://doi.org/10.1016/j.cpr.2017.09.007

Sheridan, A., Drennan, J., Coughlan, B., O'Keeffe, D., Frazer, K., & Kemple, M. et al. (2014).Improving social functioning and reducing social isolation and loneliness among people with enduring mental illness: Report of a randomised controlled trial of supported socialisation. *International Journal Of Social Psychiatry*, 61(3), 241-250. doi:10.1177/0020764014540150

Singh S. P. (2010). Early intervention in psychosis. *The British journal of psychiatry : the journal of mental science*, 196(5), 343–345. https://doi.org/10.1192/bjp.bp.109.075804

Skivington, K., Matthews, L., Simpson, S. A., Craig, P., Baird, J., Blazeby, J. M., Boyd, K. A., Craig, N., French, D. P., McIntosh, E., Petticrew, M., Rycroft-Malone, J., White, M., & Moore, L. (2021). A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *British Medical Journal (Clinical research ed.)*, *374*, n2061. https://doi.org/10.1136/bmj.n2061

Vita, A., Barlati, S., Ceraso, A., Nibbio, G., Ariu, C., Deste, G., & Wykes, T. (2021). Effectiveness, Core Elements, and Moderators of Response of Cognitive Remediation for Schizophrenia: A Systematic Review and Meta-analysis of Randomized Clinical Trials. *JAMA psychiatry*, *78*(8), 848–858. https://doi.org/10.1001/jamapsychiatry.2021.0620

Vita, A., Barlati, S., Ceraso, A., Deste, G., Nibbio, G., & Wykes, T. (2022). Acceptability of cognitive remediation for schizophrenia: a systematic review and meta-analysis of randomized controlled trials. *Psychological medicine*, 1–11. Advance online publication. https://doi.org/10.1017/S0033291722000319

Wykes, T., Huddy, V., Collard, C., McGurk, S., & Color, P. (2011). A Meta-Analysis of Cognitive Remediation for Schizophrenia: Methodology and Effect Sizes. *American Journal of Psychiatry*, 168(5), 472-485. doe: 10.1176/appi.ajp.2010.100608

Chapter 2. Social and Occupational Recovery in Early Psychosis: A Systematic Review and Meta-Analysis of Psychosocial Interventions.

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Word Count Abstract: 244

Word Count Text: 6353

Number of Figures: 2 (plus 12 Supplementary figures)

Number of Tables: 1 (plus 2 Supplementary tables)

KEYWORDS: Early Psychosis, Psychosocial Intervention, Social function, Occupational Function, Recovery.

For details of **PROSPERO** registration please see:
https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=226289

This work was funded by the Irish Health Research Board as part of the collaborative doctoral award in Youth Mental Health [YOULEAD] (HRB grant number:CDA-2018-001)

2.1 Abstract

Background: Psychosis, even in its early stages, ranks highly among causes of disability worldwide, resulting in an increased focus on improved recovery of social and occupational functioning. This study aimed to provide an estimate of the effectiveness of psychosocial interventions for improving functioning in early psychosis. We also sought evidence of superiority between intervention approaches.

Methods: An electronic search was conducted using PubMed and PsycINFO to identify original articles reporting on trials of psychosocial interventions in early-stage psychosis, published up to December 2020 and is reported following PRISMA guidelines. Data were extracted on validated measures of functioning from included studies and pooled standardised difference in means (SMD) was estimated.

Results: In total, 31 studies involving 2811 participants were included, focusing on: cognitive behavioural therapy for psychosis (CBTp), family-based therapy (FBT), supported employment, cognitive remediation training (CRT), and multi-component psychosocial interventions. Across interventions, improved function was observed (SMD = 0.239; 95% confidence interval 0.115-0.364, $p < 0.001$). Effect sizes varied by intervention type, stage of illness, length and duration of treatment and outcome measure used. In particular, interventions based on CRT significantly outperformed symptom-focused CBT interventions, while multi-component interventions were associated with largest gains.

Conclusions: Psychosocial interventions, particularly when provided as part of a multi-component intervention model and delivered in community-based settings are associated with significant improvements in social and occupational function. This review underscores the value of sensitively tracking and targeting psychosocial function as part of the standard provided by early intervention services.

DOI: https://doi.org/10.1017/S003329172100341X

2.2 Introduction

Psychosis, even in its early stages, is associated with significant disability, causing it to be ranked ahead of paraplegia and blindness in those aged 18-35 in terms of years lived with disability. Current pharmacological treatments target positive symptoms (hallucinations and delusions) of schizophrenia, but not other features of illness, including negative and affective symptoms, and cognitive deficits, which more accurately predict functional outcome than positive symptoms alone (Green, 2016). Consequently, even after successful treatment of positive symptoms, little benefit to functional outcome may result, suggesting a need to expand the range of treatment targets (Hodgekins et al., 2015; Malla & Mcgorry, 2019).

Despite this, psychosocial interventions for psychosis have often focused only on clinical/symptom improvement as the main outcome, leading to a conclusion of equivalence between psychosocial treatments in terms of modest treatment benefits (Fusar-Poli et al., 2015). However, focusing on only one illness dimension (e.g., positive symptom severity), ignores the range of factors contributing to overall loss of social/occupational function, measured in terms of reduced social engagement, and significant underemployment (~20% of individuals with psychosis go on to independent employment). In first-episode psychosis, a meta-analysis by Santesteban-Echarri et al. (2017) found that duration of untreated psychosis (DUP), cognitive function, and remission of positive and negative symptoms were each *independently* related to functional recovery (Santesteban-Echarri et al., 2017). Similarly, Stouten et al. (2017) found that poorer functioning was associated with higher levels of negative symptoms, poorer cognitive function, and poorer social cognition (explaining 39.4% of variance) (Stouten et al., 2017). We observed similar results in first-episode psychosis, and also identified premorbid adjustment as another relevant factor (Jordan et al., 2014; Jordan et al., 2018). By contrast, affective or positive symptoms did not have a marked impact on psychosocial functioning.

Here, we present a systematic review and meta-analysis of psychosocial interventions delivered during the early phase of psychosis, i.e., either during the high-risk stage, or within the five years after first diagnosis based on a range of outcomes relevant to social and occupational disability and recovery. We sought to include studies which *evaluated changes in level of social and occupational function* in early psychosis, either directly by targeting some aspect of

function, or indirectly by targeting clinical or contextual factors negatively impacting on function. These factors included: (1) clinical symptom severity, (2) hospital readmission rates, (3) levels of distress, (4) Quality of life, (5) level of cognitive function, and (6) level of social and occupational function. In addition to reviewing evidence for the efficacy and/or effectiveness of these interventions, we also sought evidence of superiority between these approaches whilst taking into consideration whether social and occupational functioning was considered a primary or secondary outcome in included studies.

2.3 Method

2.3.1 Study Selection

An electronic search was conducted using PubMed and PsycINFO to identify original articles reporting on trials of psychosocial interventions in early-stage psychosis, published up to December 2020. Early-stage psychosis was defined as including the high-risk stage, and anytime within five years of a first diagnosis of psychotic disorder. Psychosocial interventions were defined as psychologically and socially orientated interventions which targeted and then evaluated changes in level of social and occupational function (either as a primary or secondary outcome). Social and occupational functioning was assessed using one or more of the following: 1) global functioning as measured by standardised measures [e.g. Global Assessment of Function (GAF), Social and Occupational Functioning Assessment Scale (SOFAS), Social Functioning Scale (SFS)], Personal Social Performance Scale (PSP); and 2) individual definitions of functioning covering one or more of the following areas: vocational functioning, educational functioning, degree of independence and social functioning (i.e. relationships).

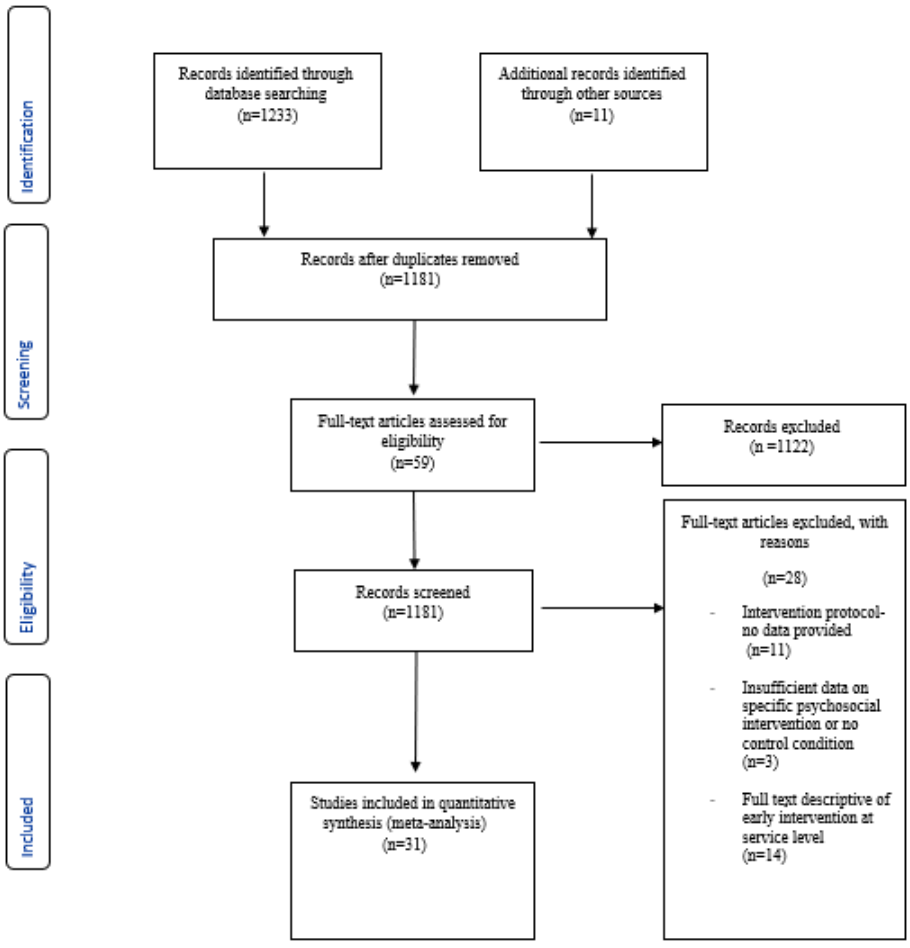
2.3.2 Search Strategy

An electronic search was conducted using PubMed and PsycINFO to identify articles investigating the effects of psychosocial interventions on psychosocial function in first-episode psychosis using the following search terms:

(“Early psychosis” OR “clinical high risk” AND “Psychosis” OR “ultra-high risk” AND “Psychosis”) OR (“first episode psychosis” OR “first episode schizophrenia” OR “recent onset psychosis” OR “recent onset schizophrenia” OR “early psychosis” OR “early schizophrenia”) AND (“social function*” OR “social outcome*” OR "global function*" OR "global outcome*" OR "community function*" OR "community outcome*" OR "occupational function*" OR

"occupational outcome*" OR "work function*" OR "work outcome*" OR "vocational function*" OR "vocational outcome*" OR “recovery” OR “quality of life” OR “employment” OR “global assessment of function” OR “social and occupational functioning assessment scale” OR “functioning scale” OR “disability”) AND (“psychosocial” OR “psychological” OR “Intervention” OR “therapy” OR “CBT” or “Cognitive behav*”OR “CRT” or “Cognitive remed*” OR “ Social” or “Social skills” OR “IPS” OR “Individual placement support” OR “Vocation*” OR “Online” OR “Moderated” or “Moderated support” OR “Family Therapy” OR “Assertive outreach” OR “Outreach” “trial” OR “program” OR “randomised control trial” OR “RCT” OR “pilot” OR “study”).Searches were limited to original, full text articles written in English and published in peer-reviewed journals up to December 2020. The initial electronic search was conducted by two authors (EF, MC). It was fully replicated in a second, independent search. No discrepancies were noted with both search results cross-checked by a third author (GD).

Figure 2.1. Prisma flow diagram of studies selected for systematic review and meta-analysis.



2.3.3 Quality assurance

The quality assessment of included studies was based on the revised version of the quality evaluation scale employed in our previous reviews as follows: (1) the clinical sample was representative of the target population (eligible cases were recruited in hospitals and/or mental health services settings with a diagnosis based on well-established clinical diagnostic manuals), (2) the clinical sample was appropriately matched to the control group (patients and controls matched for at least two confounding variables: age and/or sex and/or education level (3) the authors performed sample size calculations and/or power analysis, (4) the study used well-established measures of psychosocial functioning either as a primary or secondary outcome measure (5) the study provided adequate detail on the psychosocial intervention provided and (6) the authors reported effect sizes and/or confidence intervals (CIs) of their main findings. Each item scored one point if the criterion was met and the overall quality score was a sum of the met criteria (Rokita, Dauvermann & Donohoe, 2018).

2.3.4 Data extraction

Data were extracted on validated measures of functioning from included studies. Relevant data extracted also included study and participant characteristics (nature of the intervention, intervention length, follow-up length, control condition, number of sessions, age, percent male, diagnoses, medication use, illness duration). The authors extracted data independently and discrepancies were resolved by consensus (EF, MC, and GD).

2.3.5 Data analysis

Pooled standardised difference in means (SMD – Cohen's *d*) were estimated with Comprehensive Meta- Analysis Software (CMA), Version 3 (Borenstein, Hedges, Higgins, & Rothstein, 2013). SMD was chosen as the effect size as raw mean and standard deviation scores were provided for most included studies and to allow for the heterogeneity in functional measures used across studies. Due to the variability across studies in length of follow-up assessment, immediately post-intervention data was included in the analyses. For continuous variables, where possible, raw data (pre and post means and standard deviations) was used to estimate effect sizes. Where raw data were unavailable, sample size and F statistics were used. Two studies provided dichotomous variables for which events and sample size were used (i.e. employed *v*. unemployed). CMA allows for the inclusion of different data formats in the same analysis (Borenstein, Hedges, Higgins, & Rothstein, 2011). Effect sizes were pooled using

random-effects models. Separate analyses were conducted for five different intervention groups, and an overall summary analysis was conducted including all psychosocial intervention studies. For two intervention groups (supported employment and family-based interventions) only three studies were included in the meta-analysis, due to the small number of studies in each group these analyses should be considered exploratory. Subgroup analyses were performed to account for differences in effect size based on participant, intervention, and measurement characteristics.

2.3.6 Heterogeneity and publication bias

Heterogeneity was explored using the Q statistic and the I^2 statistics. The Q statistic measures the dispersion of all effect sizes about the mean effect size, the I^2 statistic measures the ratio of true variance to total variance (Borenstein et al., 2011). Publication bias was examined by visual inspection of funnel plots, the trim-and-fill method (Duval & Tweedie, 2000) and the regression test (Egger, Smith, Schneider, & Minder,1997).

2.3.7 Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

2.4 Results

2.4.1 Study characteristics

The literature search identified 1233 relevant publications of which 20 were found to meet inclusion criteria. A further 11 studies were identified through additional sources. In total, 31 studies involving 2811 participants were included in our analysis (see Fig 2.1 for PRISMA flow diagram and Table 2.1. for study characteristics). Studies are categorised by psychosocial intervention type as follows: cognitive behavioural therapy (CBT), family-based therapy (FBT), supported employment, cognitive remediation training (CRT) and multi-component psychosocial interventions.

Meta-analysed results for all intervention categories for which relevant data could be ascertained are presented in Figure 2 in terms of both the total effect and the effects of individual interventions where these could be estimated (n studies=31). In summary these

studies included 11 based on ultra-high-risk participants (n=1040, two studies based on prodromal patients (n=126), 11 FEP studies (n=1171), and a further seven studies of early psychosis (less than or equal to five years since diagnosis) (n=474). Participants mean age ranged from 15.5 to 29.3 years (mean=22.3, SD=3.6). Mean percentage of male participants across studies was 63.3%. Across these, 22 studies included measures of global function (GAF, SOFAS, TUS, SAS, SFS, RFS, PSP, LSP-39) four studies included measures of social functioning (GFS, SBS, social behaviour and social attainment), three studies included measures of employment, and two studies included a measure of functional capacity (UPSA-B). For a description of validated functioning measures see online supplementary Table S1. Intervention length ranged from two months to three years (mean=8.7, SD=7.7) Number of sessions ranged from 9 to 128 (mean=32.1, SD=24.2).

Across the total number of studies included, an effects size SMD = 0.239 [95% CI (0.115 to 0.364), $p<0.001$] was observed, suggesting a benefit of psychosocial interventions generally in terms of social and occupational outcomes (see Figure 2). When non-randomised control trial (RCT) studies (Mac Neil et al.,2012; McFarlane et al.,2015; Grano et al.,2016) were excluded from the analysis the effect size SMD changed to 0.251. (Grano et al.,2016; Mac Neil et al.,2012; McFarlane et al.,2015) (see online Supplementary Figure S11).

Significant heterogeneity was noted for all intervention modalities, except for CBT (see online supplementary Table S2). This is likely reflecting variability across studies in sample size, intervention length, number of sessions, participant diagnosis, and outcome measures. For CBT, CRT, and multi-component psychosocial interventions, no evidence of significant publication bias was found. Similarly, when all studies are considered together, no evidence of significant publication bias was observed. The limited number of studies in the supported employment and family-based intervention groups prevented publication bias from being thoroughly tested (See online supplementary Figures S1-4).

Table 2.1. Characteristics of studies included in the review and meta-analysis.

Study	Participants N		Mean Age (SD)	Intervention	Outcome Measures	Main Findings
	Intervention group	Control group				
Cognitive behavioural therapy						
Addington et al. (2011)	19	16	20·8 (4·5)	CBTp	GAF SAS SIAS SFS	No sig. impact on function
Bechdolf et al. (2007)	29	38	25·2 (5·3)	CBTp	SAS	Sig. improvement in SAS however no sig. diff. between CBTp and control condition.
Fowler et al. (2009)	33	38	27·8 (6·1)	SRT	Time Use	No sig. impact on function in affective psychosis group Sig. improvement in function in non-affective psychosis group 25% of individuals with non-affective psychosis engaged in paid work in the year following end of SRT
Fowler et al. (2018)	72	71	24·8 (8·3)	SRT	Time Use	SRT- > increase of 8.1 hours in structured activity
Ising et al. (2016)	80 (UHR)	90	22·7 (5·6)	CBTp	SOFAS	No sig. impact in function
Jackson et al. (2007)	31	31	22·5 (3·9)	CBTp	SOFAS	No sig. impact on function
Morrison et al. (2004)	97 (UHR)	98	22·0 (4·5)	CBTp	GAF	No sig. impact on function
Stain et al. (2016)	17 (UHR)	17	16·5 (3·2)	CBTp	GAF SOFAS	No sig. impact on function
Family-based Intervention						
Grano et al. (2016)	28 (UHR)	28	15·5 (1·6)	Family based intervention	GAF	Improvement in functioning
McFarlane et al. (2015)	147 (CHR)	57	16·4 (3·3)	Family based intervention	GAF GFR GFS	Improvement on GAF, work, and school participation
Miklowitz et al. (2014)	55 (CHR)	47	17·4 (4·1)	Family based intervention	GAF	>19 years: > improvement in GAF if received family intervention 16- 19 years: >improvement in GAF if received control condition
Supported employment						
Killackey et al. (2008)	20	21	21·3 (2·4)	IPS	Employment SOFAS	IPS > sig. higher employment and reduced welfare benefits
Killackey et al. (2019)	66	60	20·4 (2·4)	IPS	Employment SOFAS	IPS>sig. higher employment (71%)

Rosenheck et al. (2017)	144	83	23·2 (5·2)	SEE-Supported employment & education	Participation in work or school	EI associated with > increase in participation in work or school and difference appeared to be mediated by SEE
Cognitive remediation training						
Choi et al. (2016)	30 (UHR)	32	18·3 (3·7)	CRT- process speed training	SAS	Improvement in function
Eack et al. (2009/2010)	31	27	25·9 (6.3)	CRT-neurocognition + social skills group	SAS Major Role Inventory GAS	Improvement in social functioning/maintained at 1 year follow up
Lee et al. (2013)	18	18	22·8 (4·3)	CRT- Neurocognition programme + psychoeducation	SFS	CR-> improvement in function
Loewy et al. (2016)	50	33	17·8 (3·1)	CRT- auditory processing programme	GAF GFS GFR	Improvement in function
Ostergaard et al. (2014)	51	47	25·0 (3·3)	CRT- neurocognition programme	UPSA-B	No. sig. impact on function
Piskulic et al. (2015)	18 (CHR)	14	19·7 (5·7)	CRT – Auditory training	GFS GFR	Sig. improvement in social function
Ventura et al. (2017)	38	40	21·5 (3·0)	CRT- neurocognition programme + group	SAS	Sig. improvement in social functioning
Vidarsdottir et al. (2019)	25	24	24·2 (3·2)	CRT- neurocognition programme + SCIT group	LSP-39 OSA Brief A	No sig. impact on function
Wykes et al. (2007)	21	19	18·2 (2·5)	CRT – Neurocognition + TAU	SBS	Sig. impact on function
Mendella et al. (2015)	16	11	25·0 (3·9)	CCT- Compensatory Cognitive Training	UPSA-B	No sig. impact on function
Multi-component psychosocial intervention						
Albert et al. (2016)	30 (CHR)	29	26·6 (4·4)	Family treatment, social skills training, assertive treatment approach	SPS	No sig. impact on function
Mac Neil et al. (2012)	20	20	21·8 (2·1)	CBTp, family therapy, psychoeducation	GAF SOFAS	Sig. improvement in functioning
Palma et al. (2019)	35	27	25·5 (4·8)	CBTp, psychoeducation, cognitive-motivational therapy	GAF	Sig. improvement in functioning
Penn et al. (2011)	22	22	23·5 (3·9)	CBTp, psychoeducation, motivational interviewing, social skills	RFS SSPA	No sig. impact on function

Ruggeri et al. (2015)	239	153	29·3 (9·8)	CBTp, family, intervention, case management	GAF	Sig. improvement in functioning
Schlosser et al. (2018)	38	21	24·3 (2·6)	Mobile application-community peer support, CBTp, goal setting	MAP-SR RFS	Trend towards sig. diff. on MAP-SR No sig. diff. on RFS
Wessels et al. (2015)	31 (CHR)	43	25·2 (5·4)	CBTp, psychoeducation,	GAF	Sig. improvement in function.

Abbreviations: Brief-A, Behaviour Rating Inventory of Executive Function; GAF, Global Assessment of Functioning Scale; GAS, Global Assessment Scale; GFR, Global Functioning: Role Scale; GFS, Global Functioning: Social Scale; LSP-39, Life Skills Profile; OSA, Occupational Self-Assessment; MAP-SR, Motivation and Pleasure-Self Report scale; RFS, Role Functioning Scale; SAS, Social Adjustment Scale; SBS, Social Behaviour Schedule; SFS, Social Functioning Scale; SIAS, Social Interaction Anxiety Scale; SOFAS, Social & Occupational Functioning Scale; SSPA, Social Skills Performance Assessment; UPSA-B,UCSD Performance-Based Skills Assessment

2.4.2 Cognitive behavioural therapy (CBT) in at-risk and early psychosis

CBT for psychosis (CBTp) was developed with the primary aim of reducing clinical symptom severity and relapse rates, rather than to improve social and occupational function. Where social and occupational outcomes are reported, this is often as a secondary aim, if at all. CBTp is recommended by the National Institute for Health and Care Excellence for people living with a diagnosis of schizophrenia [National Institute for Health and Care Excellence (NICE), 2014]. A recent Cochrane review of CBTp concluded, however, that there remains a lack of robust evidence to support its clinical use in addition to standard care, on account of low-quality data available (Jones et al., 2018). Similarly, Bighelli et al. (2018) reported that while CBTp was associated with decreased positive symptoms, confidence in the estimates ranged from moderate to very low (Bighelli et al., 2018). Equally Laws, Darlington, Kondel, McKenna, and Jauhar (2018) in their meta-analysis reported that CBTp has a small therapeutic effect on functioning at end-of-trial, but that this benefit did not persist at follow-up (Laws et al., 2018).

Based on our review of studies carried out in early psychosis, only six studies were identified that investigated the effects of CBTp - as a single-component intervention - on social and occupational functioning. Of these, five studies focused on clinical high-risk groups, none of which found evidence that CBTp was associated with improvements on the measures of social and occupational function, which was variously measured using the GAF, SAS, SFS, Time Use and the SOFAS (Bechdolf et al., 2007;Addington et al., 2011; Ising et al., 2016; Morrison et al., 2004; Stain et al., 2016).

One study of CBTp targeted psychosocial function in first-episode psychosis (Jackson et al., 2007). It compared CBTp to a befriending intervention and demonstrated no significant difference between intervention groups post treatment (Jackson et al., 2007). Several additional studies included CBTp as one component of a multi-component intervention; these are reviewed below in the section on multi-component psychosocial interventions.

One question raised by these findings is whether a failure to see improvements in social and occupational function derives from a failure to ameliorate clinical symptoms, or whether successful improvement of clinical symptoms simply was not associated with any effects on functional outcomes. This question reflects a broader critique of CBTp in which the ability of CBT to lead to improvements in clinical state has been questioned (Fusar-Poli et al., 2015; Jones et al., 2018; Laws et al., 2018; Velthorst et al., 2015). Of the four studies above, however, each reported evidence that CBTp led to lowered symptoms, particularly positive symptoms, in the absence of a knock-on benefit to social and occupational function (Addington et al., 2011; Ising et al., 2016; Morrison et al., 2004). This was not always superior to the control condition (Stain et al., 2016). Ising et al.2016 further stating social functioning remained impaired even in those remitted from ultra-high-risk status (Ising et al., 2016).

Other approaches to CBT for psychosis have emerged over time, shifting focus from symptoms to specifically targeting social recovery. In such approaches, the emphasis is on addressing barriers to social engagement (e.g. avoidance), and participation in normative life roles. While there is much overlap with traditional CBTp in terms of collaborative formulation and goal setting, a stronger emphasis is placed on behavioural experimentation outside the clinic and in the person's own social environment to overcome identified barriers. Described as social recovery therapy (SRT), this approach has been demonstrated to lead to significant improvement in function as measured by time spent in structured activity. Importantly, this approach also showed evidence of improvements being maintained over time when compared to a control group receiving treatment a usual (Fowler et al.,2009, 2018; Fowler, Hodgekins & French, 2019). The degree to which these changes were independent of changes in symptom severity is unclear; missing data on symptom severity at follow-up assessment time points has meant that this question remains to be answered.

A meta-analysis of the effects of CBT interventions on validated measures of function was non-significant based on a total of eight available studies [SMD=0.139, 95% CI (-0.021 to

0.299), *p*=0.089] (See Figure 2). Five of these eight studies were based on UHR samples. Of note, when the analysis was conducted excluding those UHR studies a difference in effect size and significance was observed (SMD=0.345, p <0.005) (see online supplementary Figure S12). Although only three studies were included in this additional analysis, it is an important exploratory consideration.

Also noteworthy in the CBT intervention group was that the largest of these studies – based on SRT rather than a symptom-orientated CBT, was the sole individual study associated with significant gains in psychosocial function (Fowler et al., 2018).

2.4.3 Family-based interventions

Family interventions are recommended by the National Institute for Health and Care Excellence (NICE) clinical guidelines in the treatment of early psychosis [National Institute for Health and Care Excellence (NICE), 2015]. Those at-risk for or in the early stages of psychosis often continue to live with and be supported by family members in the community. It is widely acknowledged that this experience impacts not only on the individual, but also on family members in terms of their daily functioning, relationships, mental health and community interaction.

Family intervention has typically focused on relapse prevention, often by seeking to enhance communication and problem solving within the family to reduce expressed emotion, stress, and the consequent risk of relapse. Only three studies were identified that reported the effects of family therapy on social and occupational function when delivered as a sole intervention (by comparison with multi-component studies reviewed below). Each of these studies focused on clinical high-risk groups. Although the content of family intervention delivered in each study varied, key common elements of each included psychoeducation, communication skills and problem solving for everyday living. Similar to SRT, delivering family therapy as part of, or embedded in, community activities (directly in natural setting of the participant e.g. meeting in a café) featured in two of the studies and described as ‘assertive community treatment’, or ‘community-orientated integrative treatment’ (Granö et al., 2016; Mcfarlane et al., 2015). All three studies report a significant improvement in function based on both measures of social function and levels of participation in normative life activities such as school or work (Granö et al., 2016; Mcfarlane et al., 2015; Miklowitz et al., 2014). One study further compared the

impact of family therapy on psychosocial functioning between those over and under the age of 19, with a stronger treatment effect reported in those over the age of 19 (Miklowitz et al., 2014).

In terms of whether and how these effects related to changes in clinical presentation, two of the three studies reviewed report a significant reduction in symptoms, particularly positive symptoms concurrent to psychosocial improvements (Mcfarlane et al., 2015; Miklowitz et al., 2014). The third study reviewed reported improvement in psychosocial functioning, self-reported depression symptoms and hopelessness in the absence of changes in either self-reported anxiety, or psychosis risk symptoms as measured by the Structured Interview for Psychosis-Risk Syndromes (SIPS) (Granö et al., 2016).

An insufficient number of family therapy studies (n=3) were available to calculate an effects size specifically for family interventions. When reviewed in the overall list of psychosocial studies (online supplementary Figure S3), effect sizes differed between studies, with Grano et al. (2016) and Miklowitz et al. (2014) showing significant psychosocial benefits, while the study by McFarlane et al. (2015) reported non-significant benefits (Granö et al., 2016; Mcfarlane et al., 2015; Miklowitz et al., 2014). Of note also in the FBT group is that although all three studies included a control condition, both Grano et al., (2016) and McFarlane et al., (2015) are not randomised control trials and this also needs to be considered in the interpretation of the exploratory results.

2.4.4 Supported employment

Individuals with lived experience of psychosis often report they place goals of completing their education and gaining employment above addressing their mental health symptoms (Ramsay et al., 2011). Despite these stated goals, the trajectory of young people living with psychosis to complete their education and transition into employment remains low (Rinaldi et al., 2010; Waghorn et al., 2012). Under the umbrella of the supported employment model, the individual placement and support (IPS) model has been integrated into clinical guidelines and several early intervention services and represents a research focus of studies of psychosocial function in early psychosis [National Institute for Health and Care Excellence (NICE), 2015]. IPS is designed to assist people with severe mental illness to return to mainstream employment, the overarching philosophy being that anyone is capable of partaking in paid, competitive employment with careful consideration of job type, job environment and with an effective support system in place.

IPS is based on eight key principles; zero exclusion, individual job preferences, a goal of competitive employment, employers are approached with the needs of the individual in mind, provision of ongoing time-unlimited support, integration within the mental health treatment team, job search begins directly on entry into the IPS programme, and personalised benefits counselling. IPS is typically provided as part of a wider early intervention service, making the disentanglement of the effect on function difficult. Moreover, intervention components of IPS overlap to an extent with SRT and FBT in terms of psychoeducation, problem solving skills, goal formulation and notably a community-based, practical approach to recovery.

We identified three studies reporting on supported employment in early psychosis with no studies identified in relation to the clinical high-risk group. Two IPS studies in first-episode psychosis reported a significant impact on function as measured by participation in employment and reduced utilisation of welfare benefits (Killackey et al., 2019; Killackey, Jackson & McGorry, 2008). Unlike CBTp and FBT studies discussed in this review, clinical presentation, and the impact of IPS on symptom severity were not reported in these studies. Instead, the studies focused on whether recovery of social and occupational functioning was maintained over time. In particular, these studies focused on whether return to work and gains in educational attainments and were sustained over time when compared to early intervention services where staff are upskilled in vocational recovery. Similarly, a third early psychosis study took education into account, reporting on a supported employment and education intervention, informed by the broader supported employment model and IPS, combined with supported education services (Rosenheck et al., 2017). This intervention was provided in the context of an early intervention service. They report increased participation in work or school, which appears to be mediated, in part, by the supported education service.

Similar to FBT, there was an insufficient number of IPS-based studies from which to generate an intervention-specific effect size. However, as Figure S3 illustrates, the three studies included in our overall meta-analysis showed significant effects favouring the intervention groups.

2.4.5 Cognitive remediation training (CRT)

CRT is a ‘behavioural training-based intervention which aims to improve cognitive processes (attention, memory, executive function, social cognition or metacognition) with the goal of durability and generalisation’ ["Cognitive Remediation Experts Working Group (CREW)",

2010]. For schizophrenia generally, a meta-analysis of CRT reported an effect size of Cohen's d = 0.45 for cognitive performance, d = 0.42 for psycho-social functioning and d = 0.18 for symptom severity. Wykes, Huddy, Cellard, McGuck, and Czobor (2011) further concluded that CRT is more effective when provided in the context of a rehabilitation setting, allowing individuals to put their training into practice (Wykes et al., 2011). Different CRT interventions targeted a variety of perceptual and cognitive skills, including social cognition (e.g., emotion processing or facial affect recognition) with the goal of translating training into improved social and occupational functioning. A meta-analytic investigation of social cognitive training for schizophrenia in 2012 demonstrated moderate to large effects on observer-rated community and institutional function (Cohen's d= 0.78) (Kurtz & Richardson, 2012). One criticism of CRT has been the high level of the 1:1 therapy time involved. However, we have reported evidence that significant improvements in both neuropsychological function and social/occupational functioning following a computer based working memory intervention that required only weekly 1 hour 1:1 support (Donohoe et al., 2018).

What is the evidence for impact of CRT on social and occupational functioning in the clinical high-risk and early psychosis groups? Our review identified 10 studies providing a CRT intervention reporting on validated measures of function in these groups. Two studies reported on CRT in the UHR group. Piskulic, Barbato, Liu and Addington (2015) report significant improvement in function in the intervention group while Choi et al. (2016) report a non-significant impact. Interestingly both studies were computer-game based with a primary cognitive outcome however varied in terms of the intervention setting and type of functional outcome used. Piskulic et al. (2015) was delivered online and utilised a social functioning measure while Choi et al. (2016) was delivered in a traditional clinic setting and used a global measure of function. This will be considered further in the discussion below.

Five of eight studies in the early psychosis group reported evidence of a significant impact on social and occupational functioning outcomes. Of note, each of these interventions included components such as psychoeducation or a social skills group that scaffolded training e.g., by specifically relating it to greater social involvement (Eack et al., 2009; Eack, Greenwald, Hogarty, & Keshavan, 2010; Lee et al., 2013; Loewy et al., 2016; Ventura et al., 2017).

The remaining three studies in the early psychosis group reported no significant effect of the CRT intervention on psychosocial functioning (Mendella et al., 2015; Vidarsdottir et al., 2019;

Østergaard Christensen et al., 2014). In the Ostergaard et al. (2014) study a failure to observe benefits to psychosocial function was despite improvements in symptom severity, cognitive function, and self-esteem (Østergaard Christensen et al., 2014). Vidarsdottir and colleagues report no improvement on either symptoms or social functioning (Vidarsdottir et al., 2019). Similarly, Mendella et al. (2015) report improvements in cognitive domains but no impact on psychosocial functioning or symptoms (Mendella et al., 2015). An interpretation of these findings is that although all the above studies found evidence of improved cognitive function following CRT, these benefits were more likely to translate to benefits in social and occupational function when delivered alongside additional components that promoted broader recovery and greater psychosocial engagement. In short, as with CRT interventions delivered in chronic SZ, CRT in early psychosis is more likely to be beneficial when provided in the context of broader rehabilitation (e.g., early intervention services).

The data from the 10 CRT studies were available for meta-analysis, allowing us to test the significance of this intervention separately. As illustrated in Figure 2, CRT was associated with modest but significant improvements in social and occupational function when compared to control conditions [SMD=0.301, 95% CI (0.004 – 0.599), p=0.047]. As illustrated by Figure 2, difference in effect sizes reported could not be easily understood in terms of differences in sample type (first-episode/early psychosis groups *v* UHR groups).

2.4.6 Multi-component psychosocial intervention

The concept, purpose, and effectiveness of multi-component early intervention for psychosis services (EIS) has recently been described in a meta-analysis (Correll et al., 2018). As described by Corell et al. (2018) these interventions included the 'core' components of psychopharmacological treatment (with regular medication review) and family psychoeducation/counselling, alongside 'optional' components of CBT, family therapy, vocational and education counselling, social skills training, crisis management and a crisis response team. The range of intervention components was 4-6 with a mean of 4.8 (0.9) components. Important clinical outcomes in this study were considered as all-cause treatment discontinuation, hospitalisation, total and specific (positive, negative, general, depressive) symptom severity, global functioning and involvement in school or work and quality of life (Correll et al., 2018). The authors report superior outcomes for all 13 meta-analysable outcomes over treatment as usual at several time points of treatment with small to moderate effect sizes evident. In terms of social and occupational functioning, seven studies (n= 1005)

reported global functioning improving significantly more in EIS than treatment as usual (TAU) with six studies (n= 1743) also reporting significantly higher participation in school or work in EIS than TAU.

In our review of psychosocial interventions, we reviewed those studies that estimated the effects on psychosocial function of multi-component psychosocial intervention. Specifically, here, multi-component psychosocial intervention refers to studies which incorporate more than one psychosocial treatment approach from among CBTp, social skills training, family training and psychoeducation, but without the explicit inclusion of a pharmacological intervention, medication review or stipulation of core or fundamental components. In short, while it is acknowledged pharmacotherapy is frequently offered, these multi-component psychosocial interventions, rather than providing a single therapeutic approach, apply several approaches and underlying therapeutic principles with the aim of improving social and occupational functioning. Seven studies were identified under this category (see online supplementary Table S2), two based on high-risk samples and five based on individuals with early psychosis. Of the high-risk studies, Albert et al. (2016) found no evidence of improvement, despite observing that low levels of functioning were a consistent predictor of transition to psychosis (Albert et al., 2016). By comparison, Wessels et al. (2015) reported evidence of significant increase in function (as measured by the GAF scale) following a multi-component intervention (Wessels et al., 2015).

In the early psychosis group, four of the five studies report improvement in functioning in early psychosis (Macneil et al., 2012; Palma et al., 2019; Ruggeri et al., 2015; Schlosser et al., 2018). Intervention approaches in this category had the consistent features of adopting a manualised approach to the components provided and selecting individual intervention components based on the specific patients. The flexibility of intervention component selection in particular appears beneficial to individual and group outcomes in terms of psychosocial functioning; heterogeneity between these manualised approaches may present challenges in terms of replication of results and direct comparison between studies.

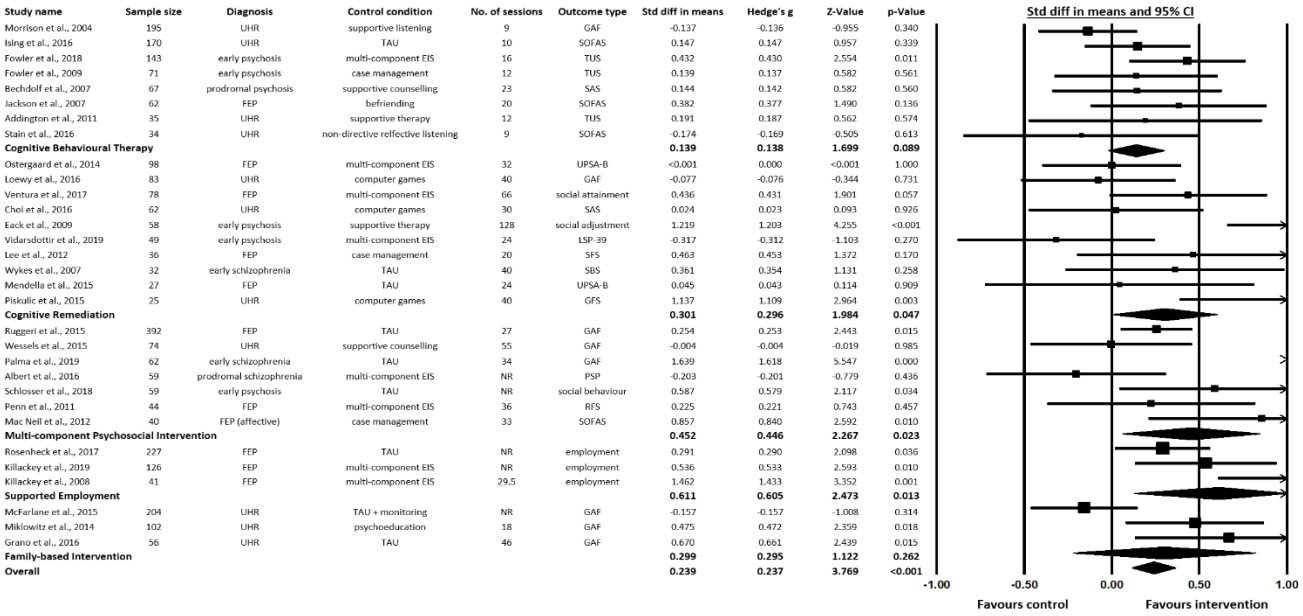
The data from the seven multi-component psychosocial studies were also available for meta-analysis. Figure 2 illustrates this group was also associated with modest but significant improvements in social and occupational functioning when compared to a control condition (SMD=0.452, 95% CI [0.061 – 0.843], p=0.023). When the non-RCT study (Mac Neil et al.,

2015) in this intervention category was excluded from the analysis the effect size standardized mean difference changed to SMD= 0.395) (see supplementary Figure S11).

2.4.7 Meta-analysis by illness stage, length and duration of intervention, and outcome measurement type

Subgroup analyses were performed to compare effect sizes based on diagnosis, length of intervention, number of sessions, control condition, mode of delivery and type of outcome measure (See supplementary Figures S5-10). When compared for diagnosis (UHR vs. FEP vs. early psychosis), the SMD was largest for the early psychosis group [SMD=0.572, 95% CI (0.129 – 1.014), p=0.011], followed by the FEP group [SMD=0.360, 95% CI (0.198 – 0.521), p<0.001], and the smallest effect size was found for UHR group [SMD=0.107,95% CI (-0.066 – 0.280), p<0.001]. For length of intervention, studies with duration of 6 months or less were compared to those with duration of greater than 6 months. Effect sizes were larger for studies with a longer duration [SMD=0.397, 95% CI (0.149 – 0.645), p=0.002] compared to studies of 6 months or less [SMD=0.251, 95% CI (0.088 – 0.415), p=0.003]. Similarly, when compared based on number of sessions, studies with >30 sessions showed a larger effect [SMD=0.487, 95% CI (0.158 – 0.816), p=0.004] than those with 30 sessions or less [SMD=0.225, 95% CI (0.077 – 0.372), p=0.003]. For control condition, studies that used an active control showed a smaller effect [SMD=0.258, 95% CI (0.091 – 0.424), p=0.002] than those that compared the intervention to TAU [SMD=0.464, 95% CI (0.194 – 0.733), p<0.001]. For mode of delivery of the intervention, community-based interventions [SMD=0.376, 95% CI (0.129 – 0.623), p=0.003] showed a larger effect than clinic-based interventions (SMD=0.264, 95% CI [0.081 – 0.447], p=0.005). Interventions delivered online showed the largest effect size [SMD=0.497, 95% CI (-0.179 – 1.174), p=0.150], however this effect was not significant and was based on only three studies. Finally, studies were grouped based on type of outcome measure used – we compared measures of general function to more specific measures of function (global function vs. social function vs. employment). There was a notable difference in effect size between these groups. Results of this subgroup analysis showed much larger effect sizes for studies that used more specific measures of employment [SMD=0.611, 95% CI (0.127 – 1.095), p=0.013] or social functioning [SMD=0.716, 95% CI (0.372 – 1.060), p<0.001] compared to global functioning measures [SMD=0.197, 95% CI (0.049 – 0.346), p=0.009].

Figure 2.2. Forest plot of summary statistics (SMD – Cohen's d) for intervention groups and overall summary statistics for psychosocial interventions.



Study name	Sample size	Diagnosis	Control condition	No. of sessions	Outcome type	Std diff in means	Hedge's g	Z-Value	p-Value
Morrison et al., 2004	195	UHR	supportive listening	9	GAF	-0.137	-0.136	-0.955	0.340
Ising et al., 2016	170	UHR	TAU	10	SOFAS	0.147	0.147	0.957	0.339
Fowler et al., 2018	143	early psychosis	multi-component EIS	16	TUS	0.432	0.430	2.554	0.011
Fowler et al., 2009	71	early psychosis	case management	12	TUS	0.139	0.137	0.582	0.561
Bechdolf et al., 2007	67	prodromal psychosis	supportive counselling	23	SAS	0.144	0.142	0.582	0.560
Jackson et al., 2007	62	FEP	befriending	20	SOFAS	0.382	0.377	1.490	0.136
Addington et al., 2011	35	UHR	supportive therapy	12	TUS	0.191	0.187	0.562	0.574
Stain et al., 2016	34	UHR	non-directive relfective listening	9	SOFAS	-0.174	-0.169	-0.505	0.613
Cognitive Behavioural Therapy						**0.139**	**0.138**	**1.699**	**0.089**
Ostergaard et al., 2014	98	FEP	multi-component EIS	32	UPSA-B	<0.001	0.000	<0.001	1.000
Loewy et al., 2016	83	UHR	computer games	40	GAF	-0.077	-0.076	-0.344	0.731
Ventura et al., 2017	78	FEP	multi-component EIS	66	social attainment	0.436	0.431	1.901	0.057
Choi et al., 2016	62	UHR	computer games	30	SAS	0.024	0.023	0.093	0.926
Eack et al., 2009	58	early psychosis	supportive therapy	128	social adjustment	1.219	1.203	4.255	<0.001
Vidarsdottir et al., 2019	49	early psychosis	multi-component EIS	24	LSP-39	-0.317	-0.312	-1.103	0.270
Lee et al., 2012	36	FEP	case management	20	SFS	0.463	0.453	1.372	0.170
Wykes et al., 2007	32	early schizophrenia	TAU	40	SBS	0.361	0.354	1.131	0.258
Mendella et al., 2015	27	FEP	TAU	24	UPSA-B	0.045	0.043	0.114	0.909
Piskulic et al., 2015	25	UHR	computer games	40	GFS	1.137	1.109	2.964	0.003
Cognitive Remediation						**0.301**	**0.296**	**1.984**	**0.047**
Ruggeri et al., 2015	392	FEP	TAU	27	GAF	0.254	0.253	2.443	0.015
Wessels et al., 2015	74	UHR	supportive counselling	55	GAF	-0.004	-0.004	-0.019	0.985
Palma et al., 2019	62	early schizophrenia	TAU	34	GAF	1.639	1.618	5.547	0.000
Albert et al., 2016	59	prodromal schizophrenia	multi-component EIS	NR	PSP	-0.203	-0.201	-0.779	0.436
Schlosser et al., 2018	59	early psychosis	TAU	NR	social behaviour	0.587	0.579	2.117	0.034
Penn et al., 2011	44	FEP	multi-component EIS	36	RFS	0.225	0.221	0.743	0.457
Mac Neil et al., 2012	40	FEP (affective)	case management	33	SOFAS	0.857	0.840	2.592	0.010
Multi-component Psychosocial Intervention						**0.452**	**0.446**	**2.267**	**0.023**
Rosenheck et al., 2017	227	FEP	TAU	NR	employment	0.291	0.290	2.098	0.036
Killackey et al., 2019	126	FEP	multi-component EIS	NR	employment	0.536	0.533	2.593	0.010
Killackey et al., 2008	41	FEP	multi-component EIS	29.5	employment	1.462	1.433	3.352	0.001
Supported Employment						**0.611**	**0.605**	**2.473**	**0.013**
McFarlane et al., 2015	204	UHR	TAU + monitoring	NR	GAF	-0.157	-0.157	-1.008	0.314
Miklowitz et al., 2014	102	UHR	psychoeducation	18	GAF	0.475	0.472	2.359	0.018
Grano et al., 2016	56	UHR	TAU	46	GAF	0.670	0.661	2.439	0.015
Family-based Intervention						**0.299**	**0.295**	**1.122**	**0.262**
Overall						**0.239**	**0.237**	**3.769**	**<0.001**

2.5 Discussion

This review and meta-analysis focused on psychosocial interventions that sought to improve to social and occupational function in the early stages of psychosis, a relatively recent and emerging focus of psychosis research. Previously, psychosocial interventions had focused either solely, or principally on reducing clinical symptoms severity as their endpoint, on the basis that this would be associated with improved functional outcomes. The absence of empirical support for this expectation has in large part informed this wider focus on and targeting of social and occupational function. As reviewed here, studies that have taken up this challenge have been varied in terms of intervention, outcome measures used, and participants. Notwithstanding this heterogeneity, broad evidence was observed to support the efficacy of psychosocial interventions for improving social and occupational function in the early stages of psychosis.

In addition to this general conclusion, several specific conclusions can also be made. Firstly, our narrative review of the available evidence suggests that delivering psychosocial intervention in community based (rather than clinic-based settings) settings is a key consideration. Community-based, assertive outreach approaches – irrespective of treatment type- appear to have a greater impact on function in the early psychosis population. Moving from clinic-based interventions towards providing treatment in the person's usual environment with involvement of key community stakeholders appears a key ingredient for effectiveness and collaborative, patient-centered working. For example, when compared to CBTp studies, where clinical improvement was not necessarily associated with improved social functioning, family-based intervention studies reporting evidence of improvement in social and occupational functioning in the clinical high-risk group tended to also report evidence of improvement in clinical presentation. One possible factor in this difference in social and occupational outcomes was the setting, with family-based interventions more likely to be delivered in the community, outside a traditional clinic setting. As noted above, social recovery orientated CBT, which is employs an assertive outreach approach and is delivered in a community setting was also found to be effective in improving social and occupational functioning (see supplementary Figure S9).

Secondly, a personalized approach to treatment that matches the psychosocial interventions provided to the needs of the individual appears critical to meeting the complex needs of individuals in the early stages of psychosis. Multi-component interventions (both at an early intervention service level and psychosocial intervention level), tailored to the needs of the individual, appear to have greater potential to impact a range of psychosocial treatment targets. Critical to the success of these multi-component interventions would appear to be the capacity to provide these components flexibly in a manner adapted to the changing needs and circumstances of individual.

In estimating the contribution of individual psychosocial intervention types, both treatment intensity and duration were observed to moderate efficacy. As noted in the findings of our meta-analysis, interventions of a 6-month duration or longer or >30 sessions were found to have a greater impact on social and occupational functioning when compared to those 6 months or less or <30 sessions (see supplementary table Figures S6 & S7).

Similarly, the type of measurement used when considering social and occupational function was observed to significantly influence the size of effect observed, with measures that specifically targeted social functioning and engagement, and employment activity yielding a more sensitive estimate of change following intervention that more global indicators (see supplementary Figure S9).

Furthermore, stage of illness – whether pre or post first diagnosis of psychosis was also observed to impact on the efficacy of treatments. In particular, improvement in psychosocial function following the interventions reviewed were greater for individuals following a diagnosis of psychotic illness (FEP or early psychosis compared to UHR). This evidence may reflect the fact that a further decline in psychosocial function following diagnosis creates a wider target for the interventions considered here to have an effect. If true, we speculate that this may not mean that interventions targeting psychosocial function are less effective in UHR or FEP group, but simply that level of social and occupational function continues to decrease during this time, thus creating a larger window of deficits in which to demonstrate recovery. This finding is considered in the context of the review limitation of the variability in defining stage of illness across studies, the impact on recruitment and inclusion criteria of individual studies, and the clinical heterogeneity of the UHR group.

As noted, a review and meta-analysis on the impact of psychosocial intervention on validated measures of function is an emerging area of research in the area of early psychosis. This study, although providing preliminary evidence of effectiveness of psychosocial intervention in this area, is not without its limitations. Firstly, we note the heterogeneity in study design and methodologies in this area of research. The quality evaluation scale (Rokita et al., 2018) employed for this review whilst meeting quality assurance standards did not account for variation in randomization and blinding and this should be considered in future reviews and meta-analyses.

A second consideration is the heterogeneity of validated measures of function ranging from global assessments to individual measure of function. The authors conclude how they measure function and considering social and occupational functioning as a primary outcome in the early psychosis group is a priority consideration in future study design. This will have potential impact on study replicability, and comparison of high-quality psychosocial intervention studies at a meta-analytical level.

Thirdly, the authors also acknowledge the lack of available data in the included studies in terms of the acceptability of the intervention to the participants and also the adherence to therapy during individual studies. Monitoring adherence to TAU, including pharmacotherapy, is also vital in future study design. These are priority considerations for future research and are likely not only to contribute to the quality of future studies but also the translation to clinical practice.

In conclusion, the increased emphasis on the value of targeting and treating social and occupational function in the early treatment of psychosis appears to be well founded. As reviewed here, there is evidence that many, but not all, psychosocial interventions are associated with improvements in these areas. We emphasize that the findings from two of the included intervention groups (FBT and IPS) are exploratory in nature due to the small number of studies included. However, we highlight that CRT, multi-component psychosocial intervention and CBT (with an emphasis on assertive outreach) emerge as providing robust evidence for clinical implementation in the early psychosis group. Providing these as part of multi-component interventions in community-based settings remains an important need for this cohort. Supporting the recent progress in increasing the availability of these interventions remains a key priority.

2.6 Supplementary material

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S003329172100341X

2.7 Funding

This work was funded by the Irish Health Research Board as part of the collaborative doctoral award in Youth Mental Health [YOULEAD] (HRB grant number:CDA-2018-001).

2.8 Conflict of Interest

None to declare.

2.9 References

Addington, J., Epstein, I., Liu, L., French, P., Boydell, K. M., & Zipursky, R. B. (2011). A randomized controlled trial of cognitive behavioral therapy for individuals at clinical high risk of psychosis. *Schizophrenia Research, 125*(1), 54-61. doi:10.1016/j.schres.2010.10.015

Albert, N., Glenthøj, L.B., Melau, M., Jensen, H., Hjorthøj, C., & Nordentoft, M. (2016). Course of illness in a sample of patients diagnosed with a schizotypal disorder and treated in a specialized early intervention setting. Findings from the 3.5 year follow-up of the OPUS II study. *Schizophrenia Research, 182,* 24-30. doi:10.1016/j.schres.2016.10.013

Bechdolf, A., Wagner, M., Veith, V., Ruhrmann, S., Pukrop, R., Brockhaus-Dumke,A., … Klosterkotter, J. (2007). Randomized controlled multicentre trial of cognitive behaviour therapy in the early initial prodromal state: effects on social adjustment post treatment.*Early Intervention in Psychiatry, 1*(1), 71-78. doi:10.1111/j.1751-7893.2007.00013.x

Bighelli, I., Salanti, G., Huhn, M., Schneider-Thoma, J., Krause, M., Reitmeir, C., … Leucht, S. (2018). Psychological interventions to reduce positive symptoms in schizophrenia: systematic review and network meta-analysis. *World psychiatry : official journal of the World Psychiatric Association (WPA), 17*(3), 316-329. doi:10.1002/wps.20577

Borenstein, M., Hedges, L., Higgins, J., & Rothstein, H. (2011). *Introduction to Meta-Analysis*. Englewood, NJ: Biostat.

Borenstein, M., Hedges, L., Higgins, J., & Rothstein, H. (2013) *Comprehensive Meta-Analysis Version 3.* Englewood, NJ: Biostat

Choi, J., Corcoran, C. M., Fiszdon, J. M., Stevens, M., Javitt, D. C., Deasy, M., … Pearlson, G. D. (2016). Pupillometer-based neurofeedback cognitive training to improve processing speed and social functioning in individuals at clinical high risk for psychosis. *Psychiatric Rehabilitation Journal, 40*(1), 33-42. doi: 10.1037/prj0000217

Correll, C. U., Galling, B., Pawar, A., Krivko, A., Bonetto, C., Ruggeri, M., … Kane, J. M. (2018). Comparison of Early Intervention Services vs Treatment as Usual for Early-Phase

Psychosis. *Journal of American Medical Association Psychiatry*, *75*(6), 555-565. doi: 10.1001/jamapsychiatry.2018.0623

Donohoe, G., Dillon, R., Hargreaves, A., Mothersill, O., Castorina, M., Furey, E., … Robertson, I. H. (2018). Effectiveness of a low support, remotely accessible, cognitive remediation training programme for chronic psychosis: cognitive, functional and cortical outcomes from a single blind randomised controlled trial. *Psychological Medicine*, *48*(5), 751-764. doi:10.1017/s0033291717001982

Duval, S., & Tweedie, R. (2000). Trim and fill: A simple funnel-plot-based method of testing and adjusting for publication bias in meta-analysis. *Biometrics*, *56*(2), 455-463. doi:10.1111/j.0006-341x.2000.00455.x

Eack, S. M., Greenwald, D. P., Hogarty, S. S., Cooley, S. J., DiBarry, A. L., Montrose, D. M., & Keshavan, M. S. (2009). Cognitive enhancement therapy for early-course schizophrenia: effects of a two-year randomized controlled trial. *Psychiatric Services*, *60*(11), 1468-1476. doi: 10.1176/appi.ps.60.11.1468

Eack, S. M., Greenwald, D. P., Hogarty, S. S., & Keshavan, M. S. (2010). One-year durability of the effects of cognitive enhancement therapy on functional outcome in early schizophrenia. *Schizophrenia Research*, *120*(1-3), 210-216. doi: 10.1016/j.schres.2010.03.042

Egger, M., Smith, G. D., Schneider, M., & Minder, C. (1997). Bias in meta-analysis detected by a simple, graphical test. *British Medical Journal (Clinical research ed.)*, *315*(7109), 629-634. doi: 10.1136/bmj.315.7109.629

Fowler, D., Hodgekins, J., & French, P. (2019). Social Recovery Therapy in improving activity and social outcomes in early psychosis: Current evidence and longer term outcomes. *Schizophrenia Research*, *203*, 99-104. doi: 10.1016/j.schres.2017.10.006

Fowler, D., Hodgekins, J., French, P., Marshall, M., Freemantle, N., McCrone, P., … Birchwood, M. (2018). Social recovery therapy in combination with early intervention services for enhancement of social recovery in patients with first-episode psychosis

(SUPEREDEN3): a single-blind, randomised controlled trial. *The Lancet Psychiatry*, *5*(1), 41-50. doi: 10.1016/S2215-0366(17)30476-5

Fowler, D., Hodgekins, J., Painter, M., Reilly, T., Crane, C., Macmillan, I., … Jones, P. B. (2009). Cognitive behaviour therapy for improving social recovery in psychosis: a report from the ISREP MRC Trial Platform Study (Improving Social Recovery in Early Psychosis). *Psychological Medicine, 39*(10), 1627-1636. doi: 10.1017/S0033291709005467

Fusar-Poli, P., Rocchetti, M., Sardella, A., Avila, A., Brandizzi, M., Caverzasi, E., … Mcguire, P. (2015). Disorder, not just state of risk: Meta-analysis of functioning and quality of life in people at high risk of psychosis. *British Journal of Psychiatry, 207*(3), 198-206. doi: 10.1192/bjp.bp.114.157115

Granö, N., Karjalainen, M., Ranta, K., Lindgren, M., Roine, M., & Therman, S. (2016). Community-oriented family-based intervention superior to standard treatment in improving depression, hopelessness and functioning among adolescents with any psychosis-risk symptoms. *Psychiatry Research, 237*, 9-16. doi:10.1016/j.psychres.2016.01.037

Green, M. F. (2016). Impact of Cognitive and Social Cognitive Impairment on Functional Outcomes in Patients with Schizophrenia. *Journal of Clinical Psychiatry, 77*(Suppl 2), 8-11.doi: 10.4088/JCP.14074su1c.02

Hodgekins, J., Birchwood, M., Christopher, R., Marshall, M., Coker, S., Everard, L., … Fowler, D. (2015). Investigating trajectories of social recovery in individuals with first-episode psychosis: a latent class growth analysis. *British Journal of Psychiatry: the journal of mental science, 207*(6), 536-543.doi: 10.1192/bjp.bp.114.153486

Ising, H. K., Kraan, T. C., Rietdijk, J., Dragt, S., Klaassen, R. M., Boonstra, N., Nieman, D. H., … Van der Gaag, M. (2016). Four-Year Follow-up of Cognitive Behavioral Therapy in Persons at Ultra-High Risk for Developing Psychosis: The Dutch Early Detection Intervention Evaluation (EDIE-NL) Trial. *Schizophrenia Bulletin, 42*(5), 1243-1252. doi: 10.1093/schbul/sbw018

Jackson, H. J., McGorry, P. D., Killackey, E., Bendall, S., Allott, K., Dudgeon, P., … Harrigan, S. (2007). Acute-phase and 1-year follow-up results of a randomized controlled trial of CBT versus Befriending for first-episode psychosis: the ACE project. *Psychological Medicine, 38*(5), 725-735. doi: 10.1017/S0033291707002061

Jones, C., Hacker, D., Meaden, A., Cormac, I., Irving, C. B., Xia, J., … Chen, J. (2018). Cognitive behavioural therapy plus standard care versus standard care plus other psychosocial treatments for people with schizophrenia. *Cochrane Database of Systematic Reviews*. *11*(11), CD008712. doi:10.1002/14651858.cd008712.pub3

Jordan, G., Lutgens, D., Joober, R., Lepage, M., Iyer, S. N., & Malla, A. (2014). The relative contribution of cognition and symptomatic remission to functional outcome following treatment of a first episode of psychosis. *Journal of Clinical Psychiatry,75*(6), 566-57.doi: 10.4088/JCP.13m08606

Jordan, G., Veru, F., Lepage, M., Joober, R., Malla, A., & Iyer, S. N. (2018). Pathways to functional outcomes following a first episode of psychosis: The roles of premorbid adjustment, verbal memory and symptom remission. *Australian and New Zealand Journal of Psychiatry*, *52*(8), 793-803. doi:10.1177/0004867417747401

Killackey, E., Allott, K., Jackson, H. J., Scutella, R., Tseng, Y. P., Borland, J., … Cotton, S. M. (2019). Individual placement and support for vocational recovery in first-episode psychosis: randomised controlled trial. *British Journal of Psychiatry*, *214*(2), 76-82. doi:10.1192/bjp.2018.191

Killackey, E., Jackson, H. J., & McGorry, P. D. (2008). Vocational intervention in first-episode psychosis: individual placement and support v. treatment as usual. *British Journal of Psychiatry, 193*(2), 114-120.doi: 10.1192/bjp.bp.107.043109

Kurtz, M. M., & Richardson, C. L. (2012). Social Cognitive Training for Schizophrenia: A Meta-Analytic Investigation of Controlled Research. *Schizophrenia Bulletin, 38*(5), 1092-1104.doi: 10.1093/schbul/sbr036

Laws, K. R., Darlington, N., Kondel, T. K., Mckenna, P. J., & Jauhar, S. (2018). Cognitive Behavioural Therapy for schizophrenia - outcomes for functioning, distress and quality of life: a meta-analysis. *Biomedicine Central Psychology*, *6*(1).doi: 10.1186/s40359-018-0243-2

Lee, R. S. C., Redoblado-Hodge, M. A., Naismith, S. L., Hermens, D. F., Porter, M. A., & Hickie, I. B. (2013). Cognitive remediation improves memory and psychosocial functioning in first-episode psychiatric out-patients. *Psychological Medicine*, *43*(6), 1161.doi: 10.1017/s0033291712002127

Loewy, R., Fisher, M., Schlosser, D. A., Biagianti, B., Stuart, B., Mathalon, D. H., & Vinogradov, S. (2016). Intensive Auditory Cognitive Training Improves Verbal Memory in Adolescents and Young Adults at Clinical High Risk for Psychosis. *Schizophrenia Bulletin*, *42*(suppl 1),118-126.doi: 10.1093/schbul/sbw009

Macneil, C. A., Hasty, M., Cotton, S., Berk, M., Hallam, K., Kader, L., … Conus, P. (2012). Can a targeted psychological intervention be effective for young people following a first manic episode? Results from an 18-month pilot study. *Early Intervention in Psychiatry*, *6*(4), 380-388.doi: 10.1111/j.1751-7893.2011.00336.x

Malla, A., & Mcgorry, P. (2019). Early Intervention in Psychosis in Young People: A Population and Public Health Perspective. *American Journal of Public Health*, *109*(3), 181-184.doi: 10.2105/ajph.2019.305018

Mcfarlane, W. R., Levin, B., Travis, L., Lucas, F. L., Lynch, S., Verdi, M., … Spring, E. (2015). Clinical and Functional Outcomes After 2 Years in the Early Detection and Intervention for the Prevention of Psychosis Multisite Effectiveness Trial. *Schizophrenia Bulletin*, *41*(1), 30-43.doi: 10.1093/schbul/sbu108

Mendella, P. D., Burton, C. Z., Tasca, G. A., Roy, P., St. Louis, L., & Twamley, E. W. (2015). Compensatory cognitive training for people with first-episode schizophrenia: Results from a pilot randomized controlled trial. *Schizophrenia Research*, *162*(1-3), 108-111.doi: 10.1016/j.schres.2015.01.016

Miklowitz, D. J., O'Brien, M. P., Schlosser, D. A., Addington, J., Candan, K. A., Marshall, C., … Cannon, T. D. (2014). Family-Focused Treatment for Adolescents and Young Adults at High Risk for Psychosis: Results of a Randomized Trial. *Journal of the American Academy of Child & Adolescent Psychiatry, 53*(8), 848-858.doi: 10.1016/j.jaac.2014.04.020

Morrison, A. P., French, P., Walford, L., Lewis, S. W., Kilcommons, A., Green, J., … Bentall, R. P. (2004). Cognitive therapy for the prevention of psychosis in people at ultra-high risk. *British Journal of Psychiatry, 185*(4), 291-297.doi: 10.1192/bjp.185.4.291

National institute for Health and Care Excellence (NICE). (2015, Feburary 12). Quality Standards for Mental Health Early Intervention Service Provision for Adults with Psychosis or Schizophrenia. Retrieved from https://www.nice.org.uk/guidance/qs80

National institute for Health and Care Excellence (NICE). (2014). Psychosis and Schizophrenia in Adults: Prevention and Management, National Clinical Practice Guidelines (CG178). Retrieved from https://www.nice.org.uk/guidance/cg178/evidence/full-guideline-490503565

Østergaard Christensen, T., Vesterager, L., Krarup, G., Olsen, B. B., Melau, M., Gluud, C., & Nordentoft, M. (2014). Cognitive remediation combined with an early intervention service in first episode psychosis. *Acta Psychiatrica Scandinavica*, *130*(4), 300-310.doi: 10.1111/acps.12287

Palma, C., Farriols, N., Frías, A., Cañete, J., Gomis, O., Fernández, M., … Signo, S. (2019). Randomized controlled trial of cognitive-motivational therapy program (PIPE) for the initial phase of schizophrenia: Maintenance of efficacy at 5-year follow up. *Psychiatry Research, 273*, 586-594. doi: 10.1016/j.psychres.2019.01.084

Penn, D. L., Uzenoff, S. R., Perkins, D, Mueser, K. T., Hamer, R, Waldheter, E, … Cook, L. (2011). A pilot investigation of the Graduated Recovery Intervention Program (GRIP) for first episode psychosis. *Schizophrenia Research,* 125(2-3), 247–256. doi: 10.1016/j.schres.2010.08.006

Piskulic, D., Barbato, M., Liu, L., & Addington, J. (2015). Pilot study of cognitive remediation therapy on cognition in young people at clinical high risk of psychosis. *Psychiatry Research, 225*(1-2), 93-98.doi: 10.1016/j.psychres.2014.10.021

Ramsay, C. E., Broussard, B., Goulding, S. M., Cristofaro, S., Hall, D., Kaslow, N. J., … Compton, M. T. (2011). Life and treatment goals of individuals hospitalized for first-episode nonaffective psychosis. *Psychiatry Research, 189*(3), 344-348. doi:10.1016/j.psychres.2011.05.039

Rinaldi, M., Killackey, E., Smith, J., Shepherd, G., Singh, S. P., & Craig, T. (2010). First episode psychosis and employment: A review. *International Review of Psychiatry, 22*(2), 148-162.doi: 10.3109/09540261003661825

Rokita, K. I., Dauvermann, M. R., & Donohoe, G. (2018). Early life experiences and social cognition in major psychiatric disorders: A systematic review. *European Psychiatry, 53*, 123-133.doi: 10.1016/j.eurpsy.2018.06.006

Rosenheck, R., Mueser, K. T., Sint, K., Lin, H., Lynde, D. W., Glynn, S. M., … Kane, J. M. (2017). Supported employment and education in comprehensive, integrated care for first episode psychosis: Effects on work, school, and disability income. *Schizophrenia Research, 182*, 120-128. doi: 10.1016/j.schres.2016.09.024

Ruggeri, M., Bonetto, C., Lasalvia, A., Fioritti, A., de Girolamo, G., Santonastaso, P., … Group, G. U. (2015). Feasibility and Effectiveness of a Multi-Element Psychosocial Intervention for First-Episode Psychosis: Results From the Cluster-Randomized Controlled GET UP PIANO Trial in a Catchment Area of 10 Million Inhabitants. *Schizophrenia Bulletin, 41*(5), 1192-1203.doi: 10.1093/schbul/sbv058

Santesteban-Echarri, O., Paino, M., Rice, S., González-Blanch, C., Mcgorry, P., Gleeson, J., & Alvarez-Jimenez, M. (2017). Predictors of functional recovery in first-episode psychosis: A systematic review and meta-analysis of longitudinal studies. *Clinical Psychology Review, 58*, 59-75.doi: 10.1016/j.cpr.2017.09.007

Schlosser, D. A., Campellone, T. R., Truong, B., Etter, K., Vergani, S., Komaiko, K., & Vinogradov, S. (2018). Efficacy of PRIME, a Mobile App Intervention Designed to Improve Motivation in Young People With Schizophrenia. *Schizophrenia Bulletin*, *44*(5), 1010-1020.doi: 10.1093/schbul/sby078

Stain, H. J., Bucci, S., Baker, A. L., Carr, V., Emsley, R., Halpin, S., … Startup, M. (2016). A randomised controlled trial of cognitive behaviour therapy versus non-directive reflective listening for young people at ultra high risk of developing psychosis: The detection and evaluation of psychological therapy (DEPTh) trial. *Schizophrenia Research*, *176*(2-3), 212-219.doi: 10.1016/j.schres.2016.08.008

Stouten, L. H., Veling, W., Laan, W., Van Der Helm, M., & Van Der Gaag, M. (2017). Psychosocial functioning in first-episode psychosis and associations with neurocognition, social cognition, psychotic and affective symptoms. *Early Intervention in Psychiatry*, *11*(1), 23-36.doi: 10.1111/eip.12210

Velthorst, E., Koeter, M., Van Der Gaag, M., Nieman, D. H., Fett, A.K. J., Smit, F., … De Haan, L. (2015). Adapted cognitive–behavioural therapy required for targeting negative symptoms in schizophrenia: meta-analysis and meta-regression. *Psychological Medicine*, *45*(3), 453-465.doi: 10.1017/s0033291714001147

Ventura, J., Subotnik, K. L., Gretchen-Doorly, D., Casaus, L., Boucher, M., Medalia, A., … Nuechterlein, K. H. (2017). Cognitive remediation can improve negative symptoms and social functioning in first-episode schizophrenia: A randomized controlled trial. *Schizophrenia Research*, *203*, 24-31.doi: 10.1016/j.schres.2017.10.005

Vidarsdottir, O. G., Roberts, D. L., Twamley, E. W., Gudmundsdottir, B., Sigurdsson, E., & Magnusdottir, B. B. (2019). Integrative cognitive remediation for early psychosis: Results from a randomized controlled trial. *Psychiatry Research*, *273*, 690-698.doi: 10.1016/j.psychres.2019.02.007

Waghorn, G., Saha, S., Harvey, C., Morgan, V. A., Waterreus, A., Bush, R., … Mcgrath, J. J. (2012). 'Earning and learning' in those with psychotic disorders: The second Australian

national survey of psychosis. *Australian & New Zealand Journal of Psychiatry*, *46*(8), 774-785.doi: 10.1177/0004867412452015

Wessels, H., Wagner, M., Frommann, I., Berning, J., Pützfeld, V., Janssen, B., … Bechdolf, A. (2015). Neuropsychological Functioning as a Predictor of Treatment Response to Psychoeducational, Cognitive Behavioral Therapy in People at Clinical High Risk of First Episode Psychosis. *Psychiatrische Praxis*, *42*(6), 313-319.doi:10.1055/s-0035-1552713

Wykes, T., Huddy, V., Cellard, C., Mcgurk, S. R., & Czobor, P. (2011). A Meta-Analysis of Cognitive Remediation for Schizophrenia: Methodology and Effect Sizes. *American Journal of Psychiatry*, *168*(5), 472-485.doi: 10.1176/appi.ajp.2010.10060855

Wykes, T., Newton, E., Landau, S., Rice, C., Thompson, N., & Frangou, S. (2007). Cognitive remediation therapy (CRT) for young early onset patients with schizophrenia: an exploratory randomized controlled trial. *Schizophrenia Research*, 94(1-3), 221–230. doi: 10.1016/j.schres.2007.03.030

Chapter 3. Cognitive Remediation and Social Recovery in Early Psychosis (CReSt-R): protocol for a pilot randomised controlled study

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Word Count Abstract: 259

Word Count Text: 3674

Number of Figures: 1 (study consort diagram)

Number of Tables: 3 (Feasibility indicators assessment,progession criteria, study outcome measures)

3.1 Abstract

Background: Psychosis, even in its early stages, is associated with significant disability, causing it to be ranked ahead of paraplegia and blindness in those aged 18-35 in terms of years lived with disability. Current pharmacological and psychological interventions have focused primarily on the reduction of positive symptoms (hallucinations and delusions), with little benefit to domains of psychosis such as cognitive difficulties and social and occupational functioning.

Methods/design: The CReSt-R intervention trial is a single center, pilot randomised controlled study based at the National University of Ireland (NUI), Galway. The trial will recruit participants from four clinical sites with assessment and intervention completed by the primary NUI Galway team. The trial will explore the feasibility, acceptability, and effectiveness of a novel psychosocial intervention for early psychosis based on a combined cognitive remediation training and cognitive behavioural therapy approach focused on social recovery. Participants, aged 16-35 within the first five years of a diagnosed psychotic disorder, will be recruited from the Children and Adolescent Mental Health Service and the Adult Mental Health Services in the region.

Discussion: Cognitive remediation training (for improving cognition) and social recovery focused cognitive behavioural therapy, have both separately demonstrated effectiveness. This trial will evaluate the feasibility, acceptability, and explore the efficacy of a treatment approach that combines both approaches as part of an integrated, multi-component intervention.

Trial Registration: Cognitive Remediation & Social Recovery in Early Psychosis (CReSt-R): ClincialTrials.gov Identifier NCT04273685. Trial registered Feb 18th, 2020. Last updated April 14th, 2021.

Keywords: Early Psychosis, Psychosocial Intervention, Social function, Occupational Function, Social Recovery, Cognitive Remediation, Pilot, Feasibility.

DOI: https://doi.org/10.1186/s40814-022-01064-6

3.2 Background

In psychosis spectrum disorders, there has been a shift in focus from research and development focused purely on pharmacological symptom management to a focus on the broader concept of recovery. Although anti-psychotic medications have been effective in symptom remission, less than half of all schizophrenia patients have been able to achieve recovery [1]. Residual impairments in both neurocognition and social cognition, unaddressed by pharmacological intervention, continue to have a significant impact on function and the rate of disability in those living with psychosis [2, 3]. The rate of development of new pharmacological interventions has slowed with no new drug released to the market in approximately 20 years.

While cognitive deficits and their impact on the social and occupational functioning are well established in chronic schizophrenia, their effects in early psychosis (defined as within the first five years of a diagnosed psychotic disorder) are less well understood. A meta-analysis recently published by our group explored cognitive predictors of social recovery in early psychosis using cross sectional and longitudinal data. The meta-analysis comprised 46 studies including 3767 participants and was based on nine cognitive domains. All cognitive domains were related to psychosocial function both cross-sectionally and longitudinally. These associations remained significant even after the effects of symptom severity, duration of untreated psychosis (DUP) and length of illness were accounted for. General cognitive ability (IQ) and social cognition were most strongly associated with both concurrent and long-term function [4].

To understand the relationship between *remission* and recovery in early psychosis, remission has been defined as referring to symptomatic and/or functional improvement over a >6-month time frame and using specific assessment criteria (The Remission in Schizophrenia Working Group RSWG criteria). *Recovery* on the other hand was defined as symptomatic and functional improvement in social, occupational, and educational domains over a time frame of >2 years [5]. In their meta-analysis of long-term outcome studies of first-episode psychosis (FEP) 58% of participants met remission criteria at a mean of five years and 38% met recovery criteria at a mean of 7.2 years.

Key elements of recovery from an individual perspective have been identified as including connectedness, hope, identity, empowerment and having a meaningful role [6]. However, these concepts are difficult to operationalise and quantify at a service level and so may get ‘lost in

translation' using conventional outcome measures, such as hospital admission rates, symptom reduction or global level of functioning.

In a systematic review and meta-analysis of 31 studies, we [7] investigated the impact of current psychosocial intervention on social and occupational functioning (both global and individual). We found that cognitive remediation training (CRT) was associated with significant gains in function, similar to chronic schizophrenia. CRT is defined as 'a behavioural training-based intervention that aims to improve cognitive processes [attention, memory, executive function, social cognition, or metacognition] with the goal of durability and generalisability' ('Cognitive Remediation Experts Workshop (CREW)', Florence, April 2010).

Cognitive behavioural therapy for psychosis (CBTp) is an evidence-based talking therapy with the primary aim of reducing clinical symptom severity e.g. hallucinations and reducing relapse rates. This type of therapy was not significantly associated with improved social and occupational. However, CBT focused on social recovery, Social Recovery Therapy (SRT), was associated with significant improvements. Multi-component interventions were found to be associated with the strongest gains in social and occupational functioning [7]. Across psychosis spectrum disorders, social cognition has been repeatedly linked to functional outcomes [8-11]. Social cognition is reported to mediate the effects of neurocognition on functional outcomes [2,12-14].

Early intervention in psychosis (EIP) services are multi-disciplinary, clinical teams established to seek, identify and reduce treatment delays at the onset of psychosis. They promote recovery by providing evidence-based intervention thereby reducing the probability of relapse following a first episode of psychosis. The concept, purpose, and effectiveness of *multi-component intervention* in EIP has been described previously [16]. These interventions included the 'core' components of psychopharmacological treatment (with regular medication review) and family psychoeducation/counselling, alongside 'optional' components of CBT, family therapy, vocational and education counselling, social skills training, crisis management and a crisis response team. Where does cognition fit in this multi-component model?

Previously, in a review of social cognitive interventions, it was concluded that in order to impact higher-order social cognitive processes, there needs to be ample opportunity for practice of skills both in a clinical setting as well as in the community [17]. Social Cognition is reported to mediate the effects of neurocognition on functional outcomes [2, 12, 14]. This suggests better functional outcomes may be achieved if both neurocognition and social cognition are targeted

in intervention and that neurocognitive training alone does not result in significant social cognitive improvements [3, 14].

The CReSt-R study investigates a novel approach to optimising the cognitive and functional benefits of psychological interventions in early psychosis. It involves a multi-component intervention that combines (a) CRT- a Computerised Interactive Remediation of Cognition-Training for Schizophrenia (CIRCuiTS) [17-19] with (b) social recovery therapy (SRT) [20-22]. In so doing, the aim is to target both social and occupational functioning and social cognition in young people living with psychosis, two outcomes of interest for this study.

CRT is recognised as an effective treatment in schizophrenia generally with a large meta-analysis reporting an effect size of Cohen's d = 0.45 for cognitive performance, d = 0.42 for psychosocial functioning and d = 0.18 for symptom severity [23]. CRT programmes have evolved over the years with a variety of programme protocols and specific techniques now reported in the literature. An expert working group, identified four core features of CRT, including facilitation by a therapist, cognitive exercise, procedures to develop problem-solving strategies, and procedures to facilitate transfer to real world functioning [24]. A meta-analysis supports this emphasis, finding that better outcomes following CRT were associated with an active and trained therapist, structured development of cognitive strategies, and integration with psychosocial rehabilitation [25]. The CIRCuiTS programme, outlined in the "Methods/design" section below, embodies these core elements. It is also informed by a metacognitive model, emphasising self-awareness, self-monitoring and self-direction when completing the programme tasks and the transfer of these skills to everyday life.

SRT is informed by cognitive behavioural theory. It is an evolved form of cognitive behavioural therapy (CBT) with an emphasis on assertive outreach and behavioural experimentation. Similar to the CIRCuiTS programme it aims to apply cognitive work and newly acquired knowledge and strategies to everyday life with a focus on self-awareness and self-monitoring.

The CReSt-R study will contribute to the cognitive remediation field and the wider field of recovery in early psychosis by exploring the feasibility, acceptability and effectiveness of this multi-component psychosocial intervention with the hypothesis of a greater impact on social and occupational functioning and social cognition compared to treatment as usual in the target group**.** Whilst both intervention components have demonstrated efficacy in previous studies in addition to being found acceptable to participants [17-22], the acceptability of the combined,

multi-component intervention to young people aged 16-35 in the early psychosis population is unknown. In addition, the feasibility of delivering the multi-component intervention and running a larger scale randomised control trial in Ireland is unknown.

3.3 Methods/design

3.3.1 Aims and objectives of the CReSt-R pilot randomised controlled study

The aim of the CReSt-R pilot randomised control study is to gather and analyse acceptability and feasibility data to (1) further develop and refine the novel, multi-component CReSt-R intervention (2) investigate the feasibility of delivering and evaluating the intervention in future definitive trials. Specifically, the study objectives (outlined in further detail in "The CReSt-R intervention and control condition", "Feasibility". "Acceptability", "Estimating treatment effect sizes" sections) include the following:

(1) To collect qualitative and quantitative data to assess the feasibility of the intervention with indicators in the areas of process, intervention, and resources.
(2) To investigate if the CReSt-R intervention is acceptable to young people, aged 16-35, who are within the first five years of a diagnosed psychotic disorder.
(3) To explore the effectiveness of the intervention by analysing primary and secondary outcome data to provide treatment effect estimates, thus informing future trial design.

3.3.2 Ethics, consent, and permissions

This study was approved by the Galway Clinical Research Ethics Committee, Merlin Park Hospital, Galway, Ireland. All participants will provide informed signed consent. The ethics application also detailed general data protection regulation (GDPR) considerations, the proposed management of vulnerable individuals in the study and assent for participants aged under 18 years of age.

3.3.3 Setting and participants

This is a community-based study and will recruit participants from the Children and Adolescent Mental Health Service (CAMHS) and the Adult Mental Health Service (AMHS). Recruitment referrals from primary care providers and self-referrals are also accepted on a case-by-case basis with a primary clinical contact deemed essential for participation. Collaboration with clinical teams is anticipated to assist with recruiting adequate number of participants for this study. A sample size of 30 is a common 'rule of thumb' in pilot studies [26, 27], with 15 in the intervention arm and 15 in the control arm considered adequate in generating data to explore

the feasibility and acceptability of the proposed intervention and in providing an estimate of the intervention's efficacy for planning a definitive intervention trial. This pragmatic approach is consistent with other feasibility studies in the area of early psychosis [28] and in line with current recommendations for pilot studies [29].

Inclusion criteria for the study are being aged between 16 and 35 years of age, within the first 5 years of a diagnosed psychotic illness (based on time since first contact with a clinical service), community based, clinically stable and having the ability to give consent. Exclusion criteria are having a history of organic impairment (including IQ <70), history of a head injury with loss of consciousness > 5-minute duration and drug abuse in the preceding month. Confirmation of diagnosis, timeframe of onset of psychotic symptoms, presence of cognitive and social and occupational difficulties will be provided via a referral form completed by the primary clinical contact. Participants may withdraw from the study at any time.

3.3.4 Study design, randomisation, and treatment allocation

A randomised pilot study with a controlled, outcome-assessor-blind, parallel- group design will be implemented. Randomisation will use a permuted block design, using a computerised random number generator with predetermined 1:1 allocation ratio and will be completed by an independent statistician. The study research assistant will provide an information sheet to a potential participant and answer any questions they may have before obtaining written consent. There will be a seven-day cooling off period between provision of consent and enrolment to the study. Upon enrolment into the study the participants will be randomised to the intervention group (CReSt-R) or the control group. Both interventions are detailed below. After randomisation, the participant will complete baseline assessments with an assessor blind to treatment allocation. All participants will be instructed not to reveal their treatment allocation prior to each follow up assessment. Should the blind be broken for any participant, this will be noted and reported to the principal investigator. The primary clinical contact for each individual participant will be informed of treatment allocation. The consort diagram for study procedure is contained in Figure 1.

3.3.5 The CreSt-R intervention and control condition

Component 1: The CRT programme used in this study is the Computerised Interactive Remediation of Cognition- Training for Schizophrenia (CIRCuiTS). CIRCuiTS is a web-based CRT programme which targets metacognition, specifically strategy use, in addition to massed practice of cognitive functions (Attention, memory and executive functioning). Collaborative

goal setting related to real-world tasks are integral to the programme with the programme tasks and exercises increasing in difficulty in response to the participant's performance and progress. The protocol for CIRCuiTS training will follow that of a previous efficacy study [19]. This will be the primary focus of 1:1 therapy for the first 4 weeks with remote practice sessions occurring between therapy visits. After 4 weeks' remote practice will continue and the focus of in-person therapy sessions will bridge to social recovery therapy as detailed below.

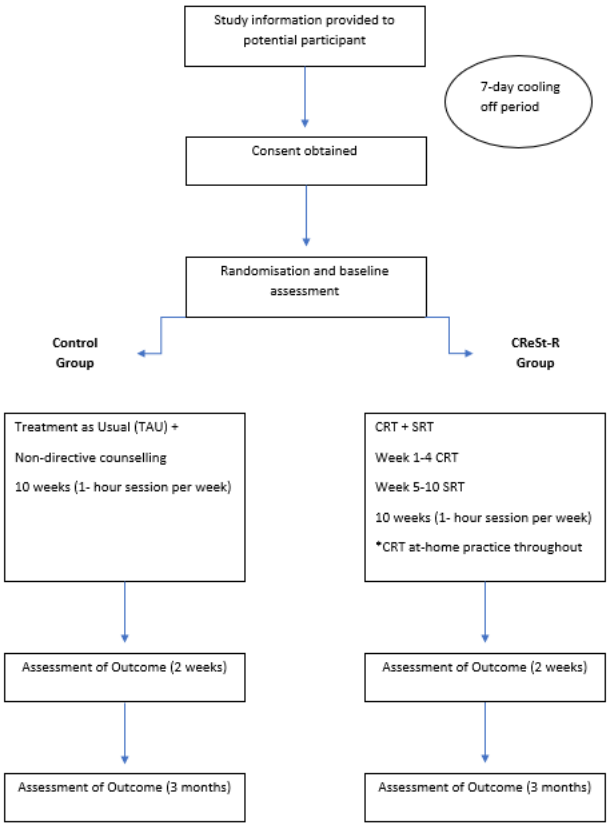
Component 2: Social recovery therapy (SRT) focuses on addressing barriers to individuals interacting in their social environment e.g., social anxiety. It is informed by cognitive behavioural theory and addresses individual goals. SRT follows an established protocol [20, 21]. In summary, this consists of therapy delivered in three stages. Stage one will include engagement and formulation with the purpose of identifying a problem list and establishing a therapeutic relationship. Stage two will include preparing for new activities with identification of pathways to activity and collaboration with community stakeholders. Stage three will include engagement in new activities using behavioural experiments to promote social activity. This is the primary focus of in-person therapy sessions from week 5 to 10 alongside remote practice of the CRT programme. There is emerging evidence to support brief intervention in both CRT [30] and CBTp [31]. Rationale for intervention duration in the CReSt-R study builds upon this recent work in addition to a previous study by our group which reported significant gains in both neuropsychological function and social function at follow up post an 8-week, low support, remotely accessible CRT programme for chronic psychosis [32]. Intervention duration will also be considered as a feasibility indicator in this study.

In the control group of the study participants will receive Treatment as Usual (TAU) plus 10 weeks of 1:1 non-directive counselling matching the intervention group for time. This consists of 10 1:1, hour-long sessions with the same intervention therapist who delivers the CRT intervention. The therapy in the control condition is characterised by empathy, unconditional positive regard, congruence, and non-directivity. Notes pertaining to each session are recorded and clinical supervision is provided by the principal investigator.

The CReSt-R intervention was initially intended for delivery in in-person sessions with a strong emphasis on assertive outreach, community-embedded intervention delivery and therapeutic rapport. However, in response to the COVID-19 pandemic and resulting public health guidelines the protocol was revised to enable adaptation to these circumstances. The outcome measures and delivery of the intervention can now be offered face to face, entirely online, or

in a blended approach remaining true to the core therapeutic principles of both components of the multicomponent intervention. These changes reflect broader change in clinical practice in response to the global pandemic and identified opportunities in this area of intervention delivery [33]. The delivery mode of the intervention will be considered in the analysis and interpretation of results.

Figure 3.1 CReSt-R Consort Diagram



3.3.6 Feasibility

All statistical analyses will occur after completion of data collection and will adopt the intention-to-treat (ITT) principle. All data will be processed in SPSS version 27. The first objective of the analysis, assessing feasibility, will consist of descriptive statistics with derivation of means and standard deviations or medians, minimum/maximum values and interquartile range for continuous measures and proportions for ordinal or multinomial categorical and binary coded measures as appropriate. Participants' baseline demographics and clinical characteristics will also be reported. Missing data patterns will be described for all three outcome time points.

Process feasibility indicators include recruitment and retention rates reported per month of trial and in total at trial completion, appropriateness of inclusion criteria and reasons for exclusion from the trial as reported by clinical collaborators, effectiveness of randomisation procedure and effectiveness of blinding procedures.

Intervention feasibility indicators include participant adherence to the trial protocol, intervention duration/therapy dosage, therapy fidelity and completion of outcome measures.

Resource feasibility indicators include therapist time in session, remote support, documentation and clinical supervision; intervention costs for software, running costs, and participant reimbursement for assessment sessions.

Table 3.1. Feasibility Indicators Assessment

Feasibility Indicator	**Assessment**
[1]Recruitment rate	% of participants recruited/time
[2]Retention rate	% of participants who complete T1, T2 & T3 outcome assessments Descriptive data on participants who leave the study early- therapy group (intervention v's control), # of sessions completed, cited reason for leaving.
Inclusion criteria	Completion rate of referral form by clinical contact Descriptive data on reasons for exclusion from study % of participants referred to study who meet inclusion criteria
Randomisation procedure	Evaluation of 1:1 ratio at end of trial (# of intervention participants: # control participants) Logged data on any errors made

Blinding procedure	Blinding in this trial will be assessed by asking blinded assessors to guess the trial group assignment and comparing these responses to what would be expected by chance Logged data on unblinding occurrences during trial
Adherence/intervention duration/therapy dosage	# of therapy sessions completed per participant Time spent on CIRCuiTS (at- home work) per participant. (logged on CIRCuiTS software platform) Time spent on at-home behavioural experiments (logged per participant throughout trial)
Therapy fidelity	Completion rate of clinical supervision sessions Completion rate of fidelity checklists
Therapist time- in session	Total time spent by therapist in session & documentation per month (data logged throughout study)
Therapist time- remote support	Total time spent communicating via email, text, or phone outside of therapy session per month (data logged throughout study)
Clinical supervision	# of clinical supervision sessions per month
Software	Total cost of CIRCuiTs license software per month
Running costs	Total cost of study expenses per month e.g. study phone
Participant reimbursement	Total cost of participant reimbursement for assessment sessions per month
[3]Qualitative study	Reflexive thematic analysis of semi-structured interview data
Intrinsic Motivation Inventory [40]	Completion rate and results of IMI

[1, 2, 3] Key feasibility indicators for progression

Criteria for progression to a larger study will be assessed using three key feasibility indicators namely (1) recruitment rate (2) retention rate and (3) acceptability of the intervention. A system of proceed, amend, or stop will be utilised modelled on previously used traffic light systems [35] (see Table 2). This system operates on the use of guidelines rather than strict thresholds in line with current recommendations [35, 37–39]. A decision to progress the trial will be decided by the above criteria, as well as discussion with the study research team, clinical collaborators, and patient–public involvement panel.

Table 3.2. Progression Criteria

Key Indicator	**Proceed**	**Amend**	**Stop**
Recruitment Rate *Target figure*: 30 participants	≥ 70 % of target number	51-69 % of target number	≤ 50% of target number
Retention Rate *Target figure*: 75% of participants randomised to intervention group will complete outcome measures at T1, T2 and T3 [53]	≥ 70 % of target number	51-69 % of target number	≤ 50% of target number
Acceptability	Intervention is described as acceptable by participants in its current form	Intervention is described as acceptable with recommended changes to improve participant experience	Intervention is described as unacceptable by participants
Action	Continue with intervention and study design with collaboration between research team, clinical collaborators, and PPI contributors	Consultation with research team, clinical collaborators, and PPI contributors regarding necessary amendments to the intervention and study design	No progression to further trial

3.3.7 Acceptability

Acceptability of the intervention will be assessed using the Intrinsic Motivation inventory (IMI) administered on completion of the study [34]. A qualitative semi-structured interview schedule has also been developed for completion at the end of the intervention (see Appendix J). This embedded qualitative study will allow participants to provide feedback focusing on the following: their general experience of participating in the intervention, intervention components, experience of recruitment, communication, and perceived benefits and challenges of participating in the intervention. The qualitative data will be analysed using a reflexive thematic analysis approach [40]. The acceptability aspect of this study will be integral in further developing the multi-component intervention and optimising clinical utility. The interview schedule itself will be reviewed for adaptation for future use based on interviewer and interviewee feedback.

3.3.8 Estimating treatment effect sizes

To clarify, this study does not aim to determine treatment effect. However, to inform statistical power calculations for primary and secondary treatment outcomes in

advance of a full RCT, estimates of treatment effect sizes will be obtained using linear mixed models. These analyses, completed in SPSS version 27, will provide a treatment

effect estimate on each outcome measure at 2 and12 weeks post-intervention. Outcome measures at these two time points will be entered into the model as the dependent variables with fixed effects of study arm, baseline outcome measures, time, and a time point by study

arm interaction. Inclusion of baseline outcome measures accounts for their potential prediction of future outcome and will contribute towards accurate effect estimates. A

random effect for participant will also be entered into the model to account for correlations between the two time points (repeated measures) per participant. This analysis will be carried out by the trial statistician.

3.3.9 Assessment battery

Primary outcome measure

Social and occupational functioning will be assessed using the Social and Occupational Functional Assessment Scale (SOFAS) [41] with an additional secondary outcome included below.

Secondary outcome measures

1. A secondary *social and occupational functioning* measure will be the Time Use Survey [42].

2. *Social cognition* will be measured using a battery of assessments based on the recommendations from the Social Cognition Psychometric Evaluation Study (SCOPE) final Validation Study [11]. These will include a) The Emotion Recognition Task (ERT) from the Cambridge Neuropsychological Test Automated Battery (Cambridge Cognition Ltd.), b) The Hinting Task [43], c) The Bell Lysaker Emotion Recognition Task (BLERT) [44], and d) the Reading the Mind in the Eyes Task [45] as operationalised in our previous CRT trial [32].

3. *Cognitive function* will be assessed in terms of general cognitive ability, memory function and executive function. General cognitive ability will be measured using the similarities and matrix reasoning subtests from the Wechsler abbreviated scale of intelligence [46]. Memory function will be assessed using the logical memory subtest and the letter number sequencing task from the Wechsler Memory scale 3rd edition [47]. Visual memory will be measured using the Rey Osterreith Complex Figure (ROCF) [48]. Executive functioning will be measured by the STROOP [49].

4. The Intrinsic Motivation Inventory for Schizophrenia Research [34] will assess intrinsic motivation and self-regulation. Subscales of the assessment will include interest/enjoyment, perceived competence, effort, value/usefulness, felt pressure and tension, and perceived choice while participating in the study.

5. The Need for Cognition Scale (NCS) [50] will assess the degree to which participants seek out cognitively challenging activities of daily living and will provide supplementary information to the social and occupational functioning outcome measures.

6.*Clinical Assessment* will include the Positive and Negative Syndrome Scale (PANSS) [51].

Table 3.3. CReSt-R Outcome Measures

Primary Outcome Measure	Social & Occupational Functioning: Social and Occupational Functional Assessment Scale (SOFAS) [41]
Secondary Outcome Measures	Function: The Time Use Survey [42] Social Cognition: CANTAB Emotion Recognition Task (ERT) The Reading the Mind in the Eyes Test [45] The Hinting Task [43] The Bell Lysaker Emotion Recognition Task (BLERT) [44] General Cognition: Wechsler Adult Scale of Intelligence 3rd edition (WAIS-III)- The similarities and matrix reasoning subtests [46] Wechsler Memory scale 3rd edition- logical memory subtest [47] Rey Osterreith Complex Figure (ROCF) [48] The Stroop Test [49] Clinical Measures: Positive and Negative Syndrome Scale (PANSS) [51] Self-report measures: The Need for Cognition Scale (NCS) [50] Intrinsic Motivation Inventory (IMI) [34]

3.4 Discussion

A strength of the protocol is the novelty of the combined intervention and in particular in the early psychosis cohort. The robust outcome assessment battery will enable us to estimate efficacy parameters for the intervention so as to inform further definitive trials in terms of social and occupational functioning, social cognition, general cognition, and other self-report measures. Data on feasibility key indicators of intervention delivery will also assist us in

exploring the potential use of the intervention in clinical practice. Potential limitations of the study include the challenge of recruitment of participants in this difficult to ascertain cohort. It is also noted the varying modes of delivery of the intervention (online, blended, in-person), whilst potentially acceptable to participants, need to be considered as part of the interpretation of data collected in the study and the potential both to inform a definitive trial and/or translate the intervention into clinical practice settings.

3.5 Declarations

3.5.1 Ethical approval This study was approved by the Galway Clinical Research Ethics Committee, Merlin Park Hospital, Galway, Ireland (reference number C.A. 2182).

3.5.2 Consent for publication Not applicable.

3.5.3 Availability of data and materials The full protocol in addition to datasets and statistical code generated during the current study will be available from the corresponding author on reasonable request.

3.5.4 Competing Interests Author TW was involved with development of the CIRCuiTS program however is not involved with supervising any of the assessment procedures or data analysis. Similarly, author DF was involved in developing Social Recovery Therapy however is also not involved in assessment procedures or data analysis.

3.5.5 Funding This work was funded by the Irish Health Research Board as part of the collaborative doctoral award in Youth Mental Health [YOULEAD] (HRB grant number:CDA-2018-001).

3.5.6 Authors' contributions EF and GD originated the conception and design of the study. EF leads the trial and will complete the analysis and interpretation of data with substantial involvement from GD also. MC, DC, ER, BH, CB, CM, DF and TW all met guidelines for authorship. All authors reviewed and approved the manuscript.

3.5.7 Acknowledgements The authors would like to acknowledge the contribution of all public and patient involvement contributors to the study to date including patients, clinicians, and the Youlead Youth Advisory Panel (YAP). We are grateful to the CIRCuiTS and SRT program developers and to the funders of this study.

3.6 References

1. Green MF. Impact of Cognitive and Social Cognitive Impairment on Functional Outcomes in Patients with Schizophrenia. J Clin Psychiatry. 2016;77(Suppl 2):8–11.

2. Fett A, Viechtbauer W, Dominguez M, Penn D, Van Os J, Krabbendam L. The relationship between neurocognition and social cognition with functional outcomes in schizophrenia: a meta-analysis. Neurosci. Biobehav.Rev. 2011;35(3):573–88.

3. Horan W, Green M. Treatment of social cognition in schizophrenia: Current status and future directions. Schizophr. Res. 2019;203:3–11.

4. Cowman M, Holleran L, Lonergan E, O'Connor K, Birchwood M, Donohoe G. Cognitive predictors of social and occupational functioning in early psychosis: a systematic review and meta-analysis of cross-sectional and longitudinal data. Schizophr. Bull. 2021;47(5):1243–53.

5. Lally J, Ajnakina O, Stubbs B, Cullinane M, Murphy KC, Gaughran F, et al. Remission and recovery from first-episode psychosis in adults: systematic review and meta-analysis of long-term outcome studies. The Br J Psychiatry : the journal of mental science. 2017;211 Suppl 6:350–8.

6. Slade M, Bird V, Le Boutillier C, Williams J, McCrone P, Leamy M. REFOCUS Trial: protocol for a cluster randomised controlled trial of a pro-recovery intervention within community based mental health teams. BMC Psychiatry. 2011;11:185.

7. Frawley E, Cowman M, Lepage M, Donohoe G. Social and occupational recovery in early psychosis: a systematic review and meta-analysis of psychosocial interventions. Psychol. Med. 2021;3:1–12.

8. Bora E, Yucel M, Pantelis C. Theory of mind impairment in schizophrenia: meta-analysis. Schizophr. Res. 2009;109:1–9.

9. Horan W, Kern R, Shokat-Fadai K, Sergi M, Wynn J, Green M. Social cognitive skills training in schizophrenia: an initial efficacy study of stabilized outpatients. Schizophr. Res. 2009;107(1):47–54.

10. Kurtz M, Richardson C. Social cognitive training for schizophrenia: a meta-analytic investigation of controlled research. Schizophr. Bull. 2012;38(5):1092–104.

11. Pinkham A, Penn D, Green M, Buck B, Healey K, Harvey P. The social cognition psychometric evaluation study: results of the expert survey and RAND panel. Schizophr. Bull. 2013;40(4):813–23.

12. Addington J, Saeedi H, Addington D. Facial affect recognition: a mediator between cognitive and social functioning in psychosis? Schizophr. Res. 2006;85(1-3):142–50.

13. McGlade N, Behan C, Hayden J, O'Donoghue T, Peel R, Haq F, et al. Mental state decoding v. mental state reasoning as a mediator between cognitive and social function in psychosis. Br J Psychiatry. 2008;193(1):77–8.

14. Green M, Horan W. Social cognition in schizophrenia. Current Directions. Psych. Sci. 2010;19(4):243–8.

15. Correll CU, Galling B, Pawar A, Krivko A, Bonetto C, Ruggeri M, et al. Comparison of early intervention services vs treatment as usual for earlyphase psychosis: a systematic review, meta-analysis, and meta-regression. JAMA Psychiatry. 2018;75(6):555–65.

16. Fiszdon JM, Reddy LF. Review of social cognitive treatment for psychosis. Clin.Psychol. Rev. 2012;32:724–40.

17. Reeder C, Wykes T. Cognitive Interaction Remediation of Cognition – a Training for Schizophrenia (CIRCuiTS). UK: King's College London; 2010.

18. Reeder C, Huddy V, Cella M, Taylor R, Greenwood K, Landau S, et al. A new generation computerised metacognitive cognitive remediation programme for schizophrenia (CIRCuiTS): a randomised controlled trial.Psych. Med. 2017;47(15):2720–30.

19. Reeder C, Pile V, Crawford P, Cella M, Rose D, Wykes T, et al. The Feasibility and Acceptability to Service Users of CIRCuiTS, a computerized cognitive remediation therapy programme for schizophrenia. Behav Cogn Psychother. 2016;44(3):288–305.

20. Fowler D, Hodgekins J, Painter M, et al. Cognitive behaviour therapy for improving social recovery in psychosis: a report from the ISREP MRC Trial Platform Study (Improving Social Recovery in Early Psychosis). Psychol Med. 2009;39:1627–36.

21. Fowler D, French P, Hodgekins J, et al. CBT to address and prevent social disability in early and emerging psychosis. In: Steel C, editor. CBT for schizophrenia: evidence-based interventions and future directions. Oxford: Wiley; 2013. p. 143–67.

22. Gee B, Notley C, Byrne R, Clarke T, Hodgekins J, French P, et al. Young people's experiences of social recovery cognitive behavioural therapy and treatment as usual in the PRODIGY trial. Early Intervention Psychiatry. 2016;12(5):879–85.

23. Wykes T, Huddy V, Cellard C, Mcgurk SR, Czobor P. A meta-analysis of cognitive remediation for schizophrenia: methodology and effect sizes. Am. J. Psychiatry. 2011;168(5):472–85.

24. Bowie CR, Bell MD, Fiszdon JM, Johannesen JK, Lindenmayer JP, McGurk SR, et al. Cognitive remediation for schizophrenia: an expert working group white paper on core techniques. Schizophr. Res. 2020;215:49–53.

25. Vita A, Barlati S, Ceraso A, et al. Effectiveness, core elements, and moderators of response of cognitive remediation for schizophrenia: a systematic review and meta-analysis of randomized clinical trials. JAMA Psychiatry. 2021;78(8):848–58.

26. Browne RH. On the use of a pilot sample for sample size determination. Stat Med. 1995;14:1933–40.

27. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. J Eval in Clin Pract. 2004;10:307–12.

28. Zisman-Ilani Y, Hurford I, Bowen A, et al. Evaluating the feasibility of a decision aid to promote shared decision making among young adults with first-episode psychosis: protocol for a pilot study. Pilot Feasibility Stud. 2021; https:// doi. org/ 10. 1186/ s40814- 020- 00757-0.

29. Leon A, Davis L, Kraemer H. The role and interpretation of pilot studies in clinical research. J Psychiatr Res. 2011;45(5):626–9.

30. Tsapekos D, Taylor R, Cella M. Feasibility and acceptability of brief cognitive remediation targeting metacognition in acute inpatients with psychosis: a case series. Neuropsychol Rehabil. 2017;29:361–75.

31. Turkington D, Munetz M, Pelton J, Montesano V, Sivec H, Nausheen B, et al. High yield cognitive behavioural techniques for psychosis delivered by case managers to their clients with persistent psychotic symptoms: anexploratory trial. J Nerv Mental Dis. 2014;1:30–4.

32. Donohoe G, Dillon R, Hargreaves A, Mothersill O, Castorina M, Furey E, et al. Effectiveness of a low support, remotely accessible, cognitive remediation training programme for chronic psychosis: cognitive, functional and cortical outcomes from a single blind randomised controlled trial. Psychol Med. 2018;48(5):751–764.

33. Torous J, Wykes T. Opportunities from the coronavirus disease 2019 pandemic for transforming psychiatric care with telehealth. JAMA Psychiatry. 2020;77(12):1205–6.

34. Choi J, Mogami T, Medalia A. Intrinsic motivation inventory: an adapted measure for schizophrenia research. Schizophr. Bull. 2010;36(5):966–76.

35. Avery K, Williamson P, Gamble C, O'Connell Francischetto E, Metcalfe C, Davidson P, et al. Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies. BMJ Open. 2017. https:// doi. org/ 10. 1136/ bmjopen- 2016- 013537.

36. Szymczynska P, Walsh S, Greenberg L, Priebe S. Attrition in trials evaluating complex interventions for schizophrenia: systematic review and meta-analysis. J Psychiatr Res. 2017;90:67–77.

37. Eldridge S, Chan C, Campbell M, Bond C, Hopewell S, Thabane L et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. Pilot Feasib Stud 2016; doi:https:// doi. org/ 10. 1136/ bmj. i5239

38. Mbuagbaw L, Kosa S, Lawson D, Stalteri R, Olaiya O, Alotaibi A, et al. The reporting of progression criteria in protocols of pilot trials designed to assess the feasibility of main trials is insufficient: a meta-epidemiological study. Pilot Feasib Stud. 2019. https:// doi. org/ 10. 1186/ s40814- 019- 0500-z.

39. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios L, et al. A tutorial on pilot studies: the what, why and how. BMC Med Res Methodol. 2010. https://doi. org/ 10. 1186/ 1471- 2288- 10-1.

40. Braun V, Clarke V. Using thematic analysis in psychology. Qual. Res. Psychol. 2006;3(2):77–101.

41. Rybarczk B. Social and Occupational functioning assessment scale (SOFAS). In: Kreutzer J, DeLuca J, Caplan B, editors. Encyclopaedia of Clinical Neuropsychology. New York: Springer; 2011. p. 2313.

42. Hodgekins J, French P, Birchwood M, Mugford M, Christopher R, Marshall M, et al. Comparing time use in individuals at different stages of psychosis and a non-clinical comparison group. Schizophrenia Res. 2015;161(2-3):188–93.

43. Corcoran R, Mercer G, Frith CD. Schizophrenia, symptomatology and social inference: Investigating “theory of mind” in people with schizophrenia. Schizophr Res. 1995;17:5–13.

44. Bryson G, Bell M, Lysaker P. Affect recognition in schizophrenia: a function of global impairment or a specifc cognitive defcit. Psychiatry Res.1997;71:105–13.

45. Baron-Cohen S, Wheelwright S, Hill J, Raste Y, Plumb I. The “Reading the Mind in the Eyes” Test revised version: a study with normal adults, and adults with Asperger syndrome or high-functioning autism. J Child Psychol Psychiatry. 2001;42:241–51.

46. Wechsler D. Wechsler Adult Intelligence Scale 3rd Ed. (WAIS-III). N.Y.: Psychological Corporation; 1997.

47. Wechsler D. Wechsler Memory Scale, 3rd edn. (WMS- III). New York: The Psychological Corporation; 1998.

48. Osterrieth PA. Le Test du copie d'une figure complexe/ Test of coping a complex figure; Contribution to the study of perception and memory. Arch Psychol. 1944;30:206–356.

49. Stroop JR. Studies of interference in serial verbal reactions. J Exp Psychol. 1935;18:643–62.

50. Cacioppo J, Petty R, Feng KC. The efficient assessment of need for cognition. J Pers Assess. 1984;48(3):306–7.

51. Kay SR, Fiszbein A, Opler LA. The positive and negative syndrome scale (PANSS) for schizophrenia. Schizophr. Bull. 1987;13(2):261–76.

Chapter 4. Cognitive Remediation and Social Recovery in Early Psychosis (CReSt-R)- results of a randomised pilot study

4.1 Introduction

Early intervention in psychosis (EIP) is recognised as providing multi-component, targeted interventions that benefit individuals living with psychosis in terms of remission, recovery, and functional trajectory (Hodgekins et al., 2015; Kane et al., 2016; Corell et al.,2018). Current clinical guidelines focus on the provision of pharmacological intervention in conjunction with several specific psychosocial interventions (namely, cognitive behavioural therapy for psychosis (CBTp), family-based interventions and supported employment) (National Institute for Health and Care Excellence (NICE), 2014,2015). Despite this, however, impairment in cognitive performance persists, is not effectively targeted by current interventions, and continue to have a significant impact on function and the rate of disability in those living with psychosis (Fett et al., 2011; Horan & Green, 2019; Cowman et al, 2021).

Among the many aspects of cognitive performance that show evidence of impairment, social cognition (those aspects of cognition relevant to understanding and interacting in social contexts) are strongly associated with functional outcomes and is therefore considered an especially important target for intervention (Bora et al., 2006; Horan et al., 2009; Kurtz et al., 2016; Pinkham et al., 2014). Social Cognition is also reported to mediate the effects of neurocognition on functional outcomes (Addington et al., 2006; McGlade et al 2008; Green & Horan, 2010, Fett et al., 2011), leading to the suggestion that better functional outcomes may be achieved when social cognition is targeted in addition to other aspects of cognitive function (Green & Horan, 2010). In a review of social cognitive interventions, Fiszdon et al. (2012) conclude that in order to impact higher-order social cognitive processes, there needs to be ample opportunity for practice of relevant socio-cognitive skills both in a clinical setting as well as in the community.

Given the evidence that cognitive and particularly social cognition may be relevant to improving social function, it is possible that better managing cognitive difficulties as part of psychosocial trials may result in improved effectiveness of psychosocial therapies. For

example, CBTp seeks to target dysfunctional beliefs by identifying and examining the evidence for and against those beliefs and replace faulty beliefs with more adaptive beliefs. Doing so is highly cognitively demanding, particularly when evidence gathering, and testing depends on social cognitive processes (e.g. attributing meaning to social interactions). Meeting the demands of a cognitively challenging intervention like CBTp has the potential to be greatly facilitated by also targeting cognitive function either alongside or as a prequel to targeting clinical symptoms. The potential benefit of doing so would be to increase patients' abilities to engage in psychosocial intervention and result in better social and occupational functioning.

The purpose of this study was to carry out a feasibility trial of a novel intervention that combined a cognitive remediation intervention targeting metacognitive skills with a CBT intervention targeting social function (the CReST-R study, standing for Cognitive remediation and Social Recovery). As outlined in the CReSt-R study protocol (Frawley et al., 2022), the purpose of the study was to achieve three key objectives (1) To collect qualitative and quantitative data to assess the feasibility of a novel multi-component intervention (outlined below) with indicators in the areas of process, intervention, and resources. (2) To investigate the acceptability of the intervention to young people, aged 16-35, in the early psychosis cohort. (3) To explore the impact of the CReSt-R intervention on social and occupational function and social cognition as two outcomes of particular interest.

4.2 Methods

4.2.1 Sample collection

Following ethical approval, a total of n = 36 participants were recruited to take part in this study (see Table 2 for demographic and clinical characteristics). Patients were recruited from the outpatient department of Galway University Hospital Adult Mental Health Service (AMHS) and Galway Child and Adolescent Mental Health Services (CAMHS).

Inclusion criteria were broad in nature for this study in line with the pragmatic approach operationalised. Inclusion criteria included being aged between 16 and 35 years of age, within the first 5 years of a diagnosed psychotic illness (based on time since first contact with a clinical service), community based, clinically stable and having the ability to give consent. Exclusion criteria were having a history of organic impairment, history of a head injury with loss of consciousness > 5-min duration and drug abuse in the preceding month. In each case,

diagnosis, timeframe of onset of psychotic symptoms, were provided by the treating team, who also provided details on cognitive and social and occupational difficulties. All participants provided informed consent prior to taking part in the study. An adverse event protocol was included in the ethics submission for this study and followed by the research team. Lone working and distress protocols were also operationalised in line with the Health Service Executive policies and procedures. There was an open line of communication between the study research assistant (MC), study lead (EF) and principal investigator (GD). Any adverse events were to be documented on a password-protected, shared study folder on the secure university server. Any concerns were to be escalated along the chain of seniority in the study and the clinical team consulted. No adverse events were recorded by the research team.

4.2.2 The CReSt-R intervention

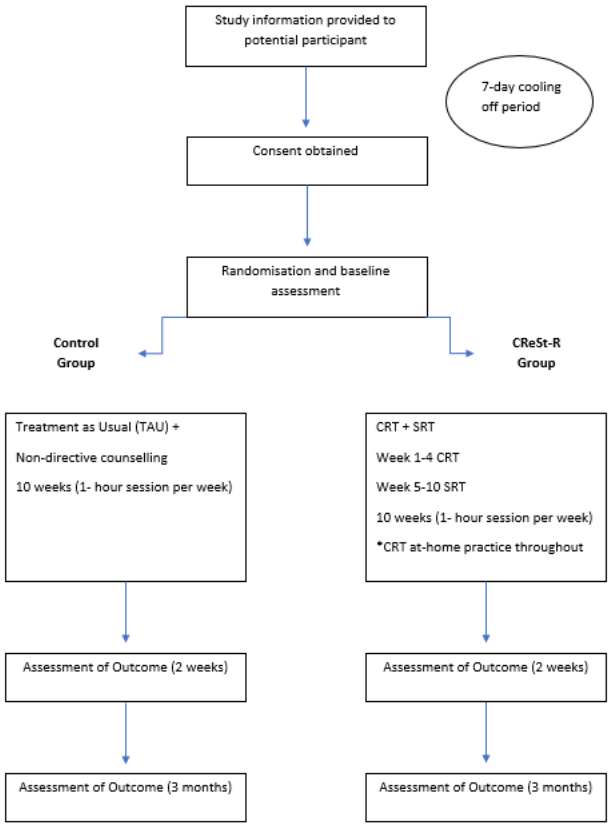
Given the high degree of complexity involved in designing, implementing, and evaluating psychosocial interventions in early psychosis, this study was informed by The Medical Research Council's (MRC; Craig et al., 2008) framework for evaluating complex interventions. The framework has more recently been updated to describe multiple components including intervention effectiveness, acceptability, cost-effectiveness, scalability, and transferability across contexts (Skivington et al., 2021). The methods employed in this randomised pilot study are guided by the MRC framework and have previously been outlined in the published study protocol (Frawley et al., 2022).

The CReSt-R intervention is a multi-component intervention combining CRT and Social Recovery Therapy (SRT), delivered in a 10-session programme. The intervention and control conditions are each detailed in the study protocol (Frawley et al., 2022) and on the trial registry (ClincialTrials.gov Identifer NCT04273685). Briefly, the CRT programme used in this study is the Computerised Interactive Remediation of Cognition-Training for Schizophrenia (CIRCuiTS). CIRCuiTS is a web-based CRT programme which targets metacognition, specifically strategy use, in addition to massed practice of cognitive functions (attention, memory, and executive functioning) and follows the protocol of a previous randomised controlled trial (Reeder et al., 2017).

The Social Recovery Therapy component is a CBT-based intervention that focuses on addressing barriers to individuals interacting in their social environment, e.g. social anxiety.

It is informed by cognitive behavioural theory and addresses individual goals. SRT also follows an established protocol (Fowler et al., 2009; Fowler et al., 2013; Fowler et al., 2019) and has been the subject of a randomised trial in its own right (Fowler et al, 2018). Finally, for the purposes of this pilot feasibility trial, the combined CReST-R intervention (i.e. CRT+SRT) was compared to a control condition. This involved treatment as usual (TAU) plus 10 weeks of 1:1 non-directive counselling, which matched the intervention group for time. This consisted of 10 1:1, hour-long sessions with the same intervention therapist who delivered the CReSt-R intervention. See Consort diagram below. The study design and protocol were reviewed with public patient involvement (PPI) collaborators, including clinicians and young people living with psychosis, at a consultation level. While ethical approval was already obtained, feedback on outcome measures, recruitment strategies, and communication approaches was incorporated into the trial design.

Figure 4.1. CReSt-R Consort Diagram



4.2.3 Outcome measures completed

Participants of the study received payment for all outcome measures assessment sessions in the form of 'one for all' gift cards as outlined in the study ethical approval documents. The outcome measures completed by all participants as part of this pilot feasibility study include the following:

Primary outcome measure

Social and occupational functioning was assessed using the Social and Occupational Functional Assessment Scale (SOFAS) (Rybarczk,2011) with an additional, functional secondary outcome included below.

Secondary outcome measures

1. A secondary *social and occupational functioning* measure was the Time Use Survey (Hodgekins et al., 2015).

2. *Social cognition* was measured using a battery of assessments based on the recommendations from the Social Cognition Psychometric Evaluation Study (SCOPE) final Validation Study (Pinkham et al., 2018). These included a) The Emotion Recognition Task (ERT) from the Cambridge Neuropsychological Test Automated Battery (Cambridge Cognition Ltd.,2017) b) The Hinting Task (Corcoran et al.,1995) c) The Bell Lysaker Emotion Recognition Task (BLERT) (Bryson et al., 1997) and d) the Reading the Mind in the Eyes Task (Baron-Cohen,2001) as operationalised in a previous CRT trial (Donohoe et al., 2018).

3. *Cognitive function* was assessed in terms of general cognitive ability, memory function and executive function. General cognitive ability was measured using the similarities and matrix reasoning subtests from the Wechsler abbreviated scale of intelligence (Wechsler,1999). Memory function was assessed using the logical memory subtest and the letter number sequencing task from the Wechsler Memory scale 3rd edition (Wechsler, 1998). Visual memory was measured using the Rey Osterreith Complex Figure (ROCF) (Osterrieth,1944). Executive functioning was measured by the STROOP (Stroop, 1935).

4. The Intrinsic Motivation Inventory for Schizophrenia Research (Choi,2010) assessed intrinsic motivation and self-regulation. Subscales of the assessment included interest/enjoyment, perceived competence, effort, value/usefulness, felt pressure and tension, and perceived choice while participating in the study.

5. The Need for Cognition Scale (NCS) (Cacioppo,1984) will assess the degree to which participants seek out cognitively challenging activities of daily living and will provide supplementary information to the social and occupational functioning outcome measures.

6.*Clinical Assessment* included the Positive and Negative Syndrome Scale (PANSS) (Kay,1987).

4.2.4 Feasibility indicators & progression criteria

A number of indicators to evaluate feasibility were outlined in the study protocol in the areas of process, intervention, and resources (see Table 1). Three key feasibility indicators were highlighted as progression criteria in this study; recruitment rate, retention rate and acceptability of the CReSt-R intervention to young people aged 16-35 years old. For recruitment, the target sample size was 30 participants, based on recommendations for pilot and feasibility studies (Browne et al.,1995; Lancaster et al., 2004; Leon et al., 2011). For progression purposes a goal of >75% of the sample target was established. For retention, a target figure of 75% of participants randomised to intervention group completing outcome measures at T0, T1 and T2 was established. This target was based on a systematic review and meta-analysis of attrition in evaluating complex interventions in schizophrenia (Szymczynska et al., 2017). (* note outcome assessment time points in the protocol publication are described as T1,T2 and T3- this corresponds to T0,T1 and T2 in this study write-up).

In addition to these feasibility criteria, the acceptability of the intervention to participants was also assessed using the Intrinsic Motivation Inventory for Schizophrenia Research (IMI) (Choi et al.,2010). This outcome measure assesses intrinsic motivation and self-regulation. Subscales of the assessment include interest/enjoyment, perceived competence, effort, value/usefulness, felt pressure and tension, and perceived choice while participating in the intervention. Of note, acceptability was also assessed qualitatively, and the results of this qualitative study are reported separately (see Frawley et al, Early Intervention in Psychiatry, submitted).

Table 4.1. Feasibility Indicators Assessment

Feasibility Indicator	**Assessment**
[1]Recruitment rate	% of participants recruited/time
[2]Retention rate	% of participants who complete T1, T2 & T3 outcome assessments Descriptive data on participants who leave the study early- therapy group (intervention v's control), # of sessions completed, cited reason for leaving.

Inclusion criteria	Completion rate of referral form by clinical contact Descriptive data on reasons for exclusion from study % of participants referred to study who meet inclusion criteria
Randomisation procedure	Evaluation of 1:1 ratio at end of trial (# of intervention participants: # control participants) Logged data on any errors made
Blinding procedure	Blinding in this trial will be assessed by asking blinded assessors to guess the trial group assignment and comparing these responses to what would be expected by chance Logged data on unblinding occurrences during trial
Adherence/intervention duration/therapy dosage	# of therapy sessions completed per participant Time spent on CIRCuiTS (at- home work) per participant. (logged on CIRCuiTS software platform) Time spent on at-home behavioural experiments (logged per participant throughout trial)
Therapy fidelity	Completion rate of clinical supervision sessions Completion rate of fidelity checklists
Therapist time- in session	Total time spent by therapist in session & documentation per month (data logged throughout study)
Therapist time- remote support	Total time spent communicating via email, text, or phone outside of therapy session per month (data logged throughout study)
Estimated running costs (excluding therapist time)	Software Total cost of CIRCuiTs license software per month Participant reimbursement- Total cost of participant reimbursement for assessment sessions per month Miscellaneous study expenses per month e.g. study phone
[3]Acceptability	Completion rate and results of the Intrinsic Motivation Inventory

[1, 2, 3] Key feasibility indicators for progression

4.2.5 Feasibility of measures of effectiveness

A fundamental objective of this pilot study was to complete exploratory statistical analysis of primary and secondary outcomes, reporting descriptive statistics, and providing treatment effect estimates. Following current guidelines on pilot and feasibility studies no formal hypothesis testing was undertaken (Eldridge et al., 2016). Rather, the purpose of this analysis is to inform future trial design, in particular estimating sample size for a definitive randomised control trial.

A linear mixed-effects model (LMM) analysis was carried out using SPSS version 27. The model was developed with a trial statistician and included fixed effects of study arm, baseline outcome measures (T0), time, and a time by study arm interaction. The random effect in the model was the individual participant number to account for correlations between the two time

points (repeated measures of T1 and T2) per participant. This type of analysis accounts for missing data at each time point and evaluates change over time in both the control and intervention groups, providing an estimated mean effect per group.

Descriptive statistics (mean and standard deviation) for all primary and secondary outcome measures at baseline (T0), post-intervention (T1) and at 3-month follow-up (T2) are provided in Table 3. Further statistical analysis was confined to outcome measures of social and occupational functioning, social cognition and symptomology as described in the results below.

Sample size, for future definitive trials, was calculated by conducting a priori power analysis using the G*power program (Faul et al., 2007, Lakens, 2022). Input parameters were set at one tailed, Cohen's d = 0.52 (based on the estimated effect on the primary outcome measure of this feasibility study (SOFAS), 80% power and alpha = 0.05. Sample size calculations for an allocation ratio of 2:1 and 1:1 are both reported.

4.3 Feasibility indicator results

4.3.1 Recruitment

A key feasibility indicator and progression criterion of this pilot study was to recruit 30 participants (Frawley et al., 2022).A total of n=36 participants with early psychosis (diagnosed less than 5 years previously) were recruited to the CReSt-R study. The majority of referrals (n=34) originated from the Adult Mental Health Service (AMHS), while two referrals came from the Child and Adolescent Mental Health Service (CAMHS). Two referrals from the AMHS did not meet inclusion criteria to progress in the study based on duration of illness, having been initially diagnosed >5 years prior to their enrollment. One participant withdrew from the study mid-way through baseline assessments, with a further five participants withdrawing before commencement of intervention (three in the control group and two in the intervention group). In total n=28 young people commenced the study intervention (see Figure 2 for a consort diagram of recruitment).

Four participants reported never participating in a psychosocial intervention in the process of their recovery. The remaining 24 participants reported sporadic interaction with private counselling services, counselling services at third level education and participating in psychosocial intervention while in inpatient care and a follow-up service post-discharge. Five participants reported ongoing psychotherapy concurrent to the study intervention. All 28

participants reported having never participated in cognitive remediation training (CRT). Baseline characteristics of participants and medication status are presented in Table 1. There were a number of interruptions to recruitment in the context of the COVID-19 pandemic and its associated public health restrictions. As a consequence, these data cannot be used to predict future recruitment patterns for replication.

Figure 4.2. Recruitment Consort Diagram

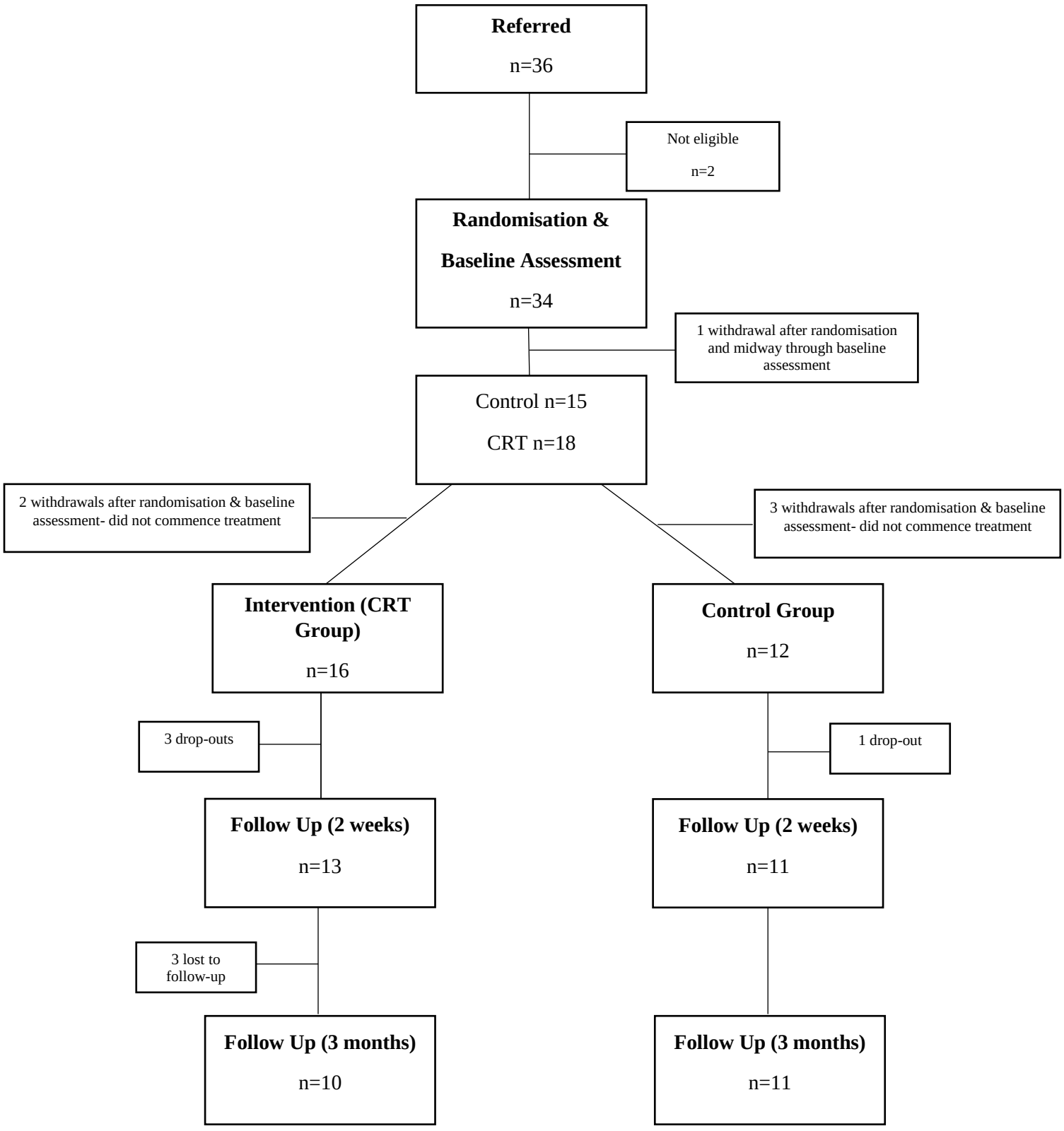


Table 4.2. Baseline demographic and clinical characteristics of the intervention and control groups.

Baseline	**Intervention Group (n=16)** **Mean (S.D.)**	**Control Group** **(n= 12)** **Mean (S.D.)**	**t-test (p-value)**
Gender (males)	7 (9)	8 (4)	$X^2 = 0.69$ (0.49)
Age	24.9 (3.2)	23.3 (5.7)	-0.90 (0.37)
Diagnosis			
Schizophrenia	3 (18.8%)	3 (25%)	
Schizoaffective disorder	3 (18.8%)	1 (8.3%)	
Bipolar disorder	2 (12.5%)	1 (8.3%)	
Other psychosis	8 (50%)	7 (58.3%)	
Age at onset	22.2 (3.3)	20.6 (6.0)	-0.90 (0.38)
Duration of illness (years)	2.6 (1.9)	2.8 (1.8)	0.180 (0.86)
Psychotic episodes	1.8 (1.1)	1.8 (1.1)	0.00 (1.00)
No. of previous hospitalisations	1.4 (1.2)	0.6 (0.7)	-2.29 (0.03)*
Medication - chlorpromazine equivalent daily dose	208.9 (128.9)	197.4 (125.5)	-0.24 (0.82)
Years in education	16.7 (2.7)	15.5 (1.9)	-1.28 (0.21)
IQ	104.4 (16.5)	95.5 (17.3)	-1.39 (0.18)
PANSS (Total)	62.2 (16.6)	67.1 (17.3)	0.76 (0.46)
SOFAS	60.9 (12.1)	57.9 (9.6)	-0.71 (0.48)

Abbreviations: IQ, Intelligence Quotient; PANSS, Positive and Negative Syndrome Scale; SOFAS, Social and Occupational Functioning Assessment Scale. *$p < 0.05$

4.3.2 Inclusion criteria

94% of participants referred to the study met inclusion criteria- two participants were inappropriately referred (both outside five years since diagnosis). Completion rate of the referral form was low and was highlighted as a barrier to timely recruitment and scheduling of baseline assessments. Referral information was primarily taken by the research assistant and intervention therapist verbally and documented thereafter.

4.3.3 Randomisation and blinding

Randomisation used a permuted block design, using a computerised random number generator with a predetermined 1:1 allocation ratio. This was completed by an independent statistician and was effective as demonstrated in Figure 2. The assessor in the study was blinded to treatment allocation. Three instances of unblinding occurred, on two occasions the participant unblinded the assessor when scheduling T1 follow-up assessment sessions. In this instance, another assessor completed both T1 and T2 assessment sessions for those participants. The third unblinding occurred after T2 assessment and before the assessor completed the blinding assessment task. In total, the assessor correctly identified treatment allocation 35.7% of the time, less than what would be expected by chance and the blinding procedure is deemed effective.

4.3.4 Retention: Six participants left the study prior to commencement of therapy intervention (see Figure 2). Of 28 individuals, who participated in either the control or intervention arm, data for 24 (86%) was available at 2-week post-treatment follow-up (T1), and 21 (79%) at 3-month post-treatment follow-up (T2).

The CReSt-R study protocol outlined a key feasibility indicator and progression criterion target of 75% of participants randomised to the intervention group completing outcome measure assessments at the three assessment time points (Frawley et al., 2022). In the intervention group, three participants left the study at the point of session five, when social recovery therapy begins.81% of participants in the intervention group completed post-intervention assessments (T1). A further 3 participants were lost to follow up with 63% completing T2 assessment. Therefore this progression criterion was met at baseline, 2-week-post-treatment follow up but not at 3-month post-treatment follow up. Retention strategies will be further discussed with collaborators for future studies with particular emphasis placed on public patient involvement (PPI). Challenges in retention will be discussed further below.

4.3.5 Acceptability: In terms of acceptability as a key component of feasibility, participants described the intervention, in its current form, as not only acceptable but engaging, helpful and person centred. Detailed information on the qualitative analysis of acceptability data is provided in Frawley et al. (Early Intervention in Psychiatry, submitted). Data from the

Intrinsic Motivation Inventory (IMI) was initially intended to supplement the qualitative study as outlined in the study protocol. A decision was made however, not to include the IMI results due to the sporadic nature of recruitment, assessment and intervention delivery in the context of the COVID-19 pandemic. The reliability and validity of the IMI data in relation to the CReSt-R intervention therefore was questioned and a quality control decision was made to not include this data.

The results of the key feasibility indicators and progression criteria of recruitment, retention and acceptability targets indicate feasibility to proceed to a definitive trial with particular emphasis on retention strategies in study design.

4.4 Statistical analysis results

4.4.1 Exploratory linear mixed-effects model analysis

Exploratory linear mixed-effects model (LMM) analysis demonstrated that both control and intervention groups were found to improve on a number of social and occupational functioning, social cognitive and symptom outcome measures over the duration of the study and follow-up time points. However, there was no significant difference observed between the control and intervention group across outcome measures (see Figure 3 for primary outcome measure results). Paired sample t-tests were then completed to test pre-post treatment changes within the intervention group only and to further inform future trial design. These are described next.

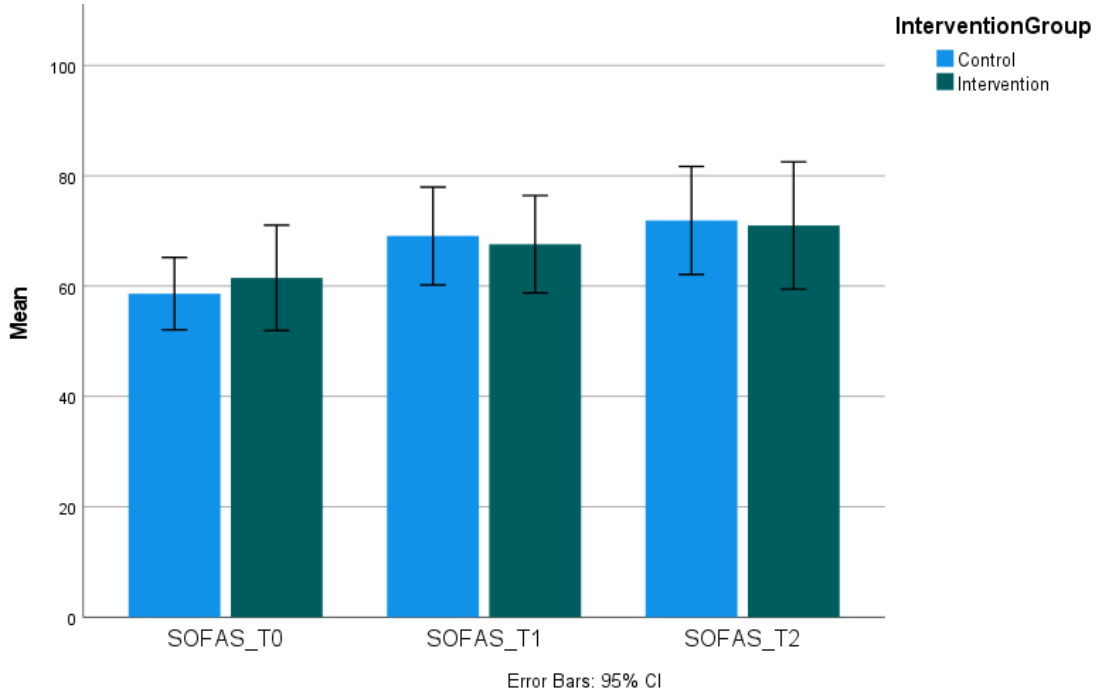


Figure 4.3. Treatment Effects on Social and Occupational Functioning Scale (SOFAS).

4.4.2 Social and occupational function (intervention group only)

The primary outcome measure for this randomised pilot study was the Social and Occupational Functioning scale (SOFAS) (Rybarczk et al., 2011). As mentioned, no significant difference in change was found between the intervention and control group post-intervention (T1) or at follow-up (T2) in the LMM analysis. Paired sample t-tests were used to explore intervention treatment effects at both follow-up time points (T1 and T2). A significant improvement in SOFAS scores from baseline to post-intervention was observed ($t(12)=-3.31$, $p<0.01$;$d= 0.52$,Table 4). There was no significant difference in SOFAS performance from post-intervention to follow-up (Figure 3).

The Time Use Survey (Hodgekins et al.,2015) was included as a secondary outcome measure of function. No significant changes were observed at either follow up time points for the intervention group in both constructive economic activity and structured activity (Table 4).

4.4.3 Social cognition (intervention group only)

Four social cognition measures were used in this pilot study, based on recommendations from the Social Cognition Psychometric Evaluation Study (Pinkham et al., 2014). A significant improvement from baseline to post-intervention was observed for one social cognition measure; the Bell Lysaker Emotion Recognition Task (BLERT) ($t(12)=-4.61$, $p\leq0.01$;$d=1.31$).No significant effect was found for the other social cognition measures (Table 4). There was no significant change in BLERT performance from post-intervention to follow-up (Figure 4).

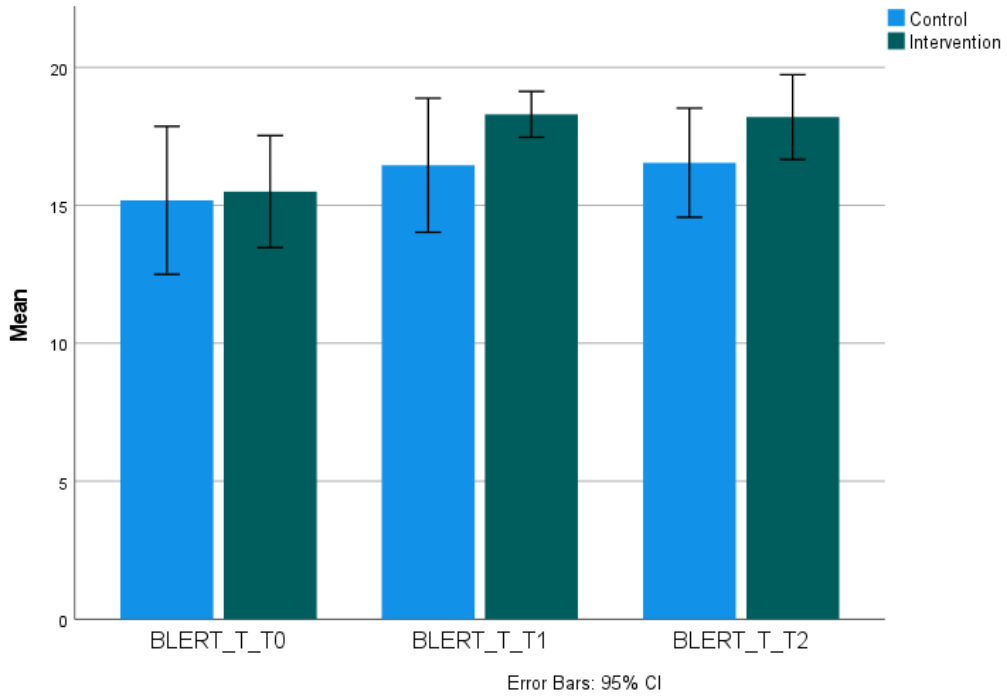


Figure 4.4. Treatment Effects on Bell Lysaker Emotion Recognition Task (BLERT)

4.4.4 Symptoms (intervention group only)

Symptoms of psychosis were assessed using the Positive and Negative Syndrome Scale (PANSS). A significant improvement from baseline to post-intervention was observed for the PANSS total score ($t(12)=2.52$, $p<0.05$;$d=0.70$).Significant effects were noted in the individual dimensions of general symptoms ($t(12)= 2.89$, $p<0.02$;$d=0.80$) and positive symptoms ($t(12)= 3.01$, $p<0.02$;$d=0.83$) (Table 4). There were no significant differences in total, general and positive dimension scores from post-intervention to follow-up (Figure 5). For negative symptoms there was no significant improvement from baseline to post-intervention however, a significant improvement was observed from post-intervention to 3-month follow-up ($t(9)=2.22$, $p\leq0.05$;$d=0.70$,Table 4).

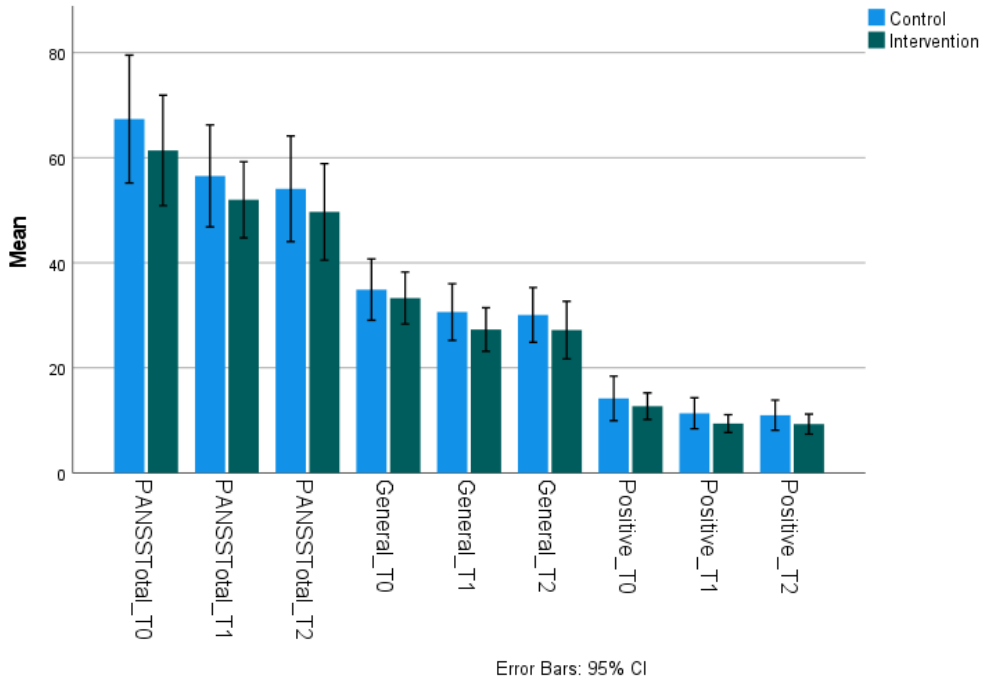


Figure 4.5. Treatment Effects on Positive and Negative Syndrome Scale (Total, General and Positive Dimensions).

Figure 4.6. Treatment Effects on Positive and Negative Syndrome Scale (Negative Symptoms)

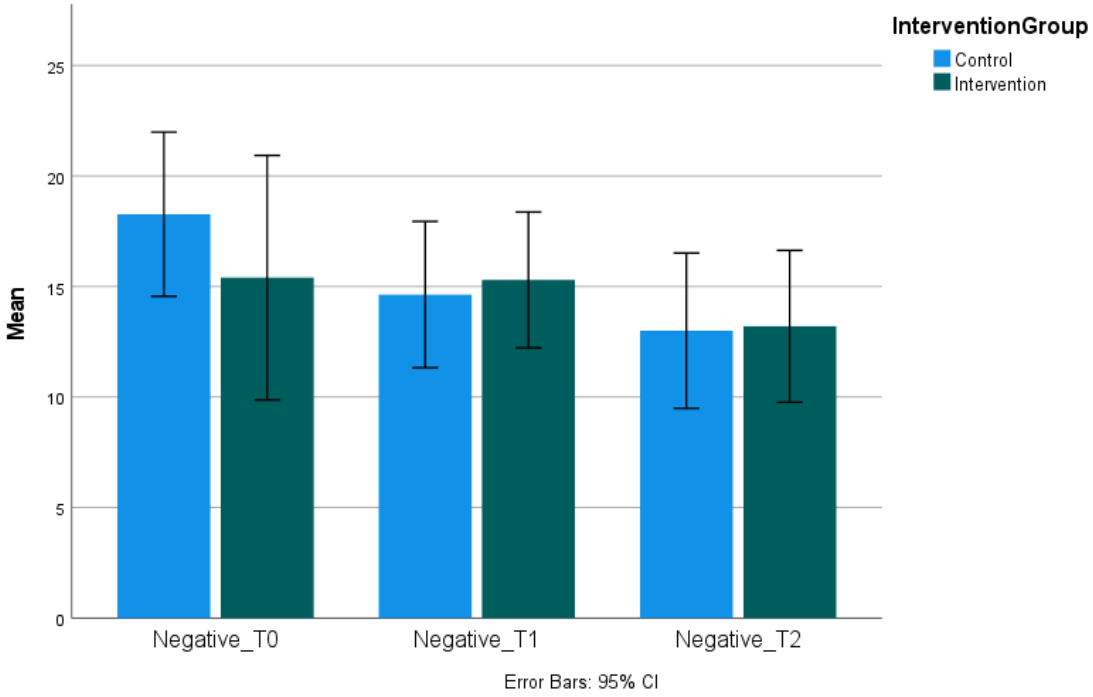


Table 4.4. Pre-post CReSt-R Intervention Treatment Effect Size

(Intervention group only)

	T0 Baseline Mean (S.D.)	T1 Post-treatment Mean (S.D.)	Effect Size T0-T1 Cohen's d	Confidence Interval 95%	T2 3-month Follow up Mean (S.D.)	Effect Size T1-T2 (Cohen's d)	Confidence Interval 95%
Function							
SOFAS	61.92 (12.3)	68.00 (10.9)	0.52	-1.09-0.07	71.00 (16.1)	0.24	-0.86-0.40
TUS (SA)	37.58 (19.3)	35.88 (16.9)	0.09	-0.45-0.64	37.5 (23.3)	0.12	-0.74-0.51
TUS (CEA)	21.68 (18.2)	22.62 (18.1)	0.05	-0.59-0.50	25.49 (17.8)	0.14	-0.78-0.49
Social Cognition							
ERT (Total correct hits)	29.91 (4.5)	30.25 (3.8)	0.05	-0.57-0 67	31.10 (5.8)	0.10	-0.72-0.52
RMET	23.0 (5.5)	25.85 (6.0)	0.38	-0.94-0.19	25.5 (4.8)	0.11	-0.51-0.73
Hinting	14.19 (2.8)	15.23 (1.4)	0.30	-0.85-0.26	16.10 (3.1)	0.32	-0.95-0.32
BLERT (Total)	15.56 (2.9)	18.54 (1.3)	1.31	-2.05-0.54	18.20 (2.2)	0.06	-0.56-0.68
Symptoms							
PANSS-Total	62.19 (16.6)	52.15 (9.9)	0.70	0.08-1.30	49.70 (12.8)	0.42	-0.24-1.06
PANSS-General	32.81 (7.6)	27.46 (6.6)	0.80	0.16-1.42	27.20 (7.7)	0.03	-0.59-0.65
PANSS-Positive	13.06 (3.7)	09.23 (2.2)	0.83	0.19-1.46	09.30 (2.7)	0.04	-0.58-0.66
PANSS-Negative	16.31 (7.9)	15.46 (4.3)	0.12	-0.67-0.43	13.20 (4.8)	0.70	-0.1-1.38

Abbreviations: BLERT, Bell Lysaker Emotion Recognition Task; ERT, Emotion Recognition Task; PANSS, Positive and Negative Syndrome Scale; RMET, Reading the Mind in the Eyes Task; SD, Standard Deviation; SOFAS, Social and Occupational Functioning Assessment Scale; TUS (CEA), Time Use Survey (constructive economic activity); TUS (SA), Time Use Survey (structured activity).

4.4.5 Estimating sample size based on observed effect size

In order to detect a between groups effect size of Cohen's d >or =0.52 with 80% power (alpha=0.05, one-tailed), the estimated required sample size required is 94 (i.e. 47 participants in the intervention group, 47 participants in the control group (allocation ratio of 1:1). Using an allocation rate of 2:1, a sample size of n=106 is estimated to be required (n=72 in the intervention group and n=35 in the control group). A one-tailed test was conducted rather than a two-tailed test, as there is a hypothesised direction of improvement on the primary outcome measure utilised in future definitive trials. It is hypothesised there will be a greater improvement in the CReSt-R intervention group V's control group in future definitive trials.

Table 4.3. Descriptive statistics of intervention and control groups

Outcome Measure	T0-Baseline		T1-Post-treatment		T2- 3-month Follow-up	
	Intervention Mean (S.D.) N= 16	Control Mean (S.D.) N=12	Intervention Mean (S.D.) N= 13	Control Mean (S.D.) N= 11	Intervention Mean (S.D.) N= 10	Control Mean (S.D.) N= 11
Function						
SOFAS	60.94 (12.1)	57.92 (9.6)	68.00 (10.9)	69.09 (13.2)	71.00 (16.1)	71.91 (14.6)
Time Use Survey (structured activity)	37.24 (18.9)	48.88 (20.75)	35.88 (16.9)	49.36 (21.70)	37.5 (23.3)	47.21 (17.96)
Time Use Survey (Constructive economic activity)	21.68 (18.2)	30.54 (21.8)	22.62 (18.1)	31.60 (21.0)	25.49 (17.8)	33.88 (19.2)
Social Cognition						
ERT (Total correct hits)	29.91 (4.5)	28.10 (4.7)	30.25 (3.8)	29.09 (6.8)	31.10 (5.8)	29.91 (5.2)
BLERT (Total)	15.56 (2.9)	15.17 (3.8)	18.54 (1.3)	16.45 (3.6)	18.20 (2.2)	16.55 (2.9)
RMET	23.0 (5.5)	25.92 (6.3)	25.85 (6.0)	25.91 (3.8)	25.5 (4.8)	25.91 (3.9)
Hinting	14.19 (2.8)	11.75 (3.4)	15.23 (1.4)	15.09 (2.9)	16.10 (3.1)	16.55 (2.5)
Symptoms						
PANSS-Total	62.19 (16.6)	67.08 (17.3)	52.15 (9.9)	56.55 (14.4)	49.70 (12.8)	54.09 (15.0)
PANSS-General	32.81 (7.6)	34.42 (8.5)	27.46 (6.6)	30.64 (8.0)	27.20 (7.7)	30.09 (7.8)
PANSS- Positive	13.06 (3.7)	14.17 (6.0)	09.23 (2.2)	11.36 (4.4)	09.30 (2.7)	11.00 (4.3)
PANSS-Negative	16.31 (7.9)	18.50 (5.3)	15.46 (4.3)	14.64 (4.9)	13.20 (4.8)	13.00 (5.2)
Cognitive Function						
FIQ	104.44 (16.5)	95.50 (17.3)	109.92 (14.4)	105.73 (20.1)	112.30 (17.6)	103.18 (20.0)
WAIS-III Similarities subtest	10.81 (2.4)	10.17 (2.8)	11.15 (1.6)	10.82 (3.8)	11.60 (2.0)	11.18 (3.9)
WAIS-III Matrix Reasoning subtest	11.56 (3.7)	10.42 (3.6)	12.69 (2.5)	11.91 (3.0)	12.20 (3.2)	11.18 (2.8)
WMS-III Letter Number Sequencing subtest	8.69 (3.3)	6.75 (1.9)	9.54 (3.6)	8.64 (3.7)	10.50 (3.9)	8.27 (2.5)
WMS-III Logical Memory-immediate	7.50 (2.5)	6.42 (4.1)	10.15 (3.5)	7.18 (4.5)	10.70 (3.6)	8.09 (4.0)
WMS-III Logical Memory-delayed	6.75 (3.4)	6.25 (4.7)	10.23 (3.4)	7.64 (5.1)	11.10 (3.5)	9.18 (3.9)
STROOP – response latency	78.07 (147.0)	90.0 (86.7)	72.69 (84.2)	66.18 (131.0)	132.80 (204.2)	71.00 (112.5)
ROCF- copy	33.72 (4.0)	32.04 (4.3)	33.78 (3.3)	33.73 (3.2)	33.90 (2.6)	34.27 (2.2)
ROCF- recall	19.59 (7.7)	17.96 (7.1)	24.81 (7.3)	19.86 (9.2)	26.10 (8.1)	23.73 (8.4)
ROCF- delayed recall	19.06 (7.4)	17.10 (7.1)	23.12 (7.7)	17.91 (8.7)	27.00 (7.3)	22.59 (8.7)
Self-Report Measures						
NCS	13.87 (28.6)	- 0.67 (27.2)	9.85 (28.30)	-3.27 (31.05)	10.40 (32.6)	2.91 (30.5)
IMI- Interest	N/A		5.55 (1.3)	5.51 (1.2)	5.79 (1.24)	5.89 (0.99)
IMI- Effort	N/A		5.57 (1.4)	4.40 (1.4)	5.56 (1.35)	4.70 (1.2)
IMI- Pressure	N/A		5.37 (1.7)	5.41 (1.5)	6.00 (1.12)	5.56 (1.4)
IMI- Choice	N/A		6.26 (1.0)	6.19 (1.4)	5.61 (1.68)	6.40 (0.5)
IMI- Value	N/A		6.30 (1.1)	5.87 (1.3)	6.19 (1.00)	5.96 (1.1)

Abbreviations: BLERT, Bell Lysaker Emotion Recognition Task; ERT, Emotion Recognition Task; FIQ, Full-scale Intelligence Quotient; IMI, Intrinsic Motivation Inventory; NCS, Need for Cognition Scale; PANSS, Positive and Negative Syndrome Scale; RMET, Reading the Mind in the Eyes Task; ROCF, Rey Osterreith Complex Figure; SD, Standard Deviation; SOFAS, Social and Occupational Functioning Assessment Scale; WAIS-III, Wechsler Adult Intelligence Scale 3rd Edition; WMS-111, Wechsler Memory Scale, 3rd Edition

4.5 Discussion

This randomised pilot study examined the feasibility of a novel, multi-component intervention that combined cognitive remediation training and social recovery therapy in a ten-week intervention. To our knowledge it is the first of its kind in the early psychosis cohort. Overall, the intervention and study design were deemed feasible in terms of key indicators outlined in the study protocol (Frawley et al., 2022). Specifically, progression criteria of recruitment and retention were satisfactorily met, building on evidence already presented of the acceptability of the intervention to participants (Frawley et al., Early Intervention in Psychiatry, submitted). Additional indicators in the area of process (inclusion criteria, blinding and randomisation procedures) were also deemed feasible.

Retention of participants was slightly below the progression criterion established in the study protocol with an attrition rate of 19% at T1 and 37% at T2. While this was deemed acceptable in terms of progression, it is important to consider the attrition rate as a proxy of acceptability of the intervention and place it in context of other research trials in psychosis. In a meta-analysis of attrition in trials evaluating non-pharmacological, complex interventions for schizophrenia, an overall attrition rate of 14% was reported, albeit with high heterogeneity across studies also noted (Szymczynska et al., 2017). Sub-group analyses further reported an attrition rate of 25% for CBT interventions,24% for cognitive interventions and 34% for novel or 'other' interventions. More recently, another meta-analysis by Vita et al. (2022) reported an overall attrition rate in CRT in Schizophrenia trials as 16.58%. In an Irish context, a previous randomised control trial of a CRT programme alone, reported an attrition rate of 47.9% at T1 and 68.8% at T2 (Donohoe et al., 2018) while a Compliance Therapy RCT reported attrition rates of 3.5% at T1 and 7.14% at T2 (O'Donnell et al., 2003). It should be noted the later RCT was delivered in an in-patient setting.

A final consideration when interpreting retention in the CReSt-R study is that the vast majority of recruitment, assessment and intervention delivery occurred during the COVID-19 pandemic and evolving public health guidelines, and restrictions. In the initial stages of the pandemic, the assessment battery and intervention were adapted to be delivered online via a secure platform (university of Galway Zoom account, data was stored on the university server and password protected) following professional guidelines (The British Psychological Society, 2020). Assertive outreach sessions continued to be offered in community settings

which remained open to the public, and at University Hospital, Galway following public health guidelines and with consent from the participant. Opportunities for social interaction online, meaningful to the individual participant, were also explored e.g. the therapist attended an online 'meet up' group with a participant and continued to work on goals specific to cognition and SRT in this setting. Given the significant challenges associated with delivering a psychosocial intervention in the context of a global pandemic, the retention rate of CReSt-R is considered successful. No adverse events were recorded by the study team throughout the study. However, a study limitation may be that sufficient detail on reasons for attrition was not obtained. There is potential an adverse event may have occurred that impacted a participant's ability to engage with the intervention but not accurately recorded or documented by the study team. This will be considered in future trials and the management of participants leaving a study.

Overall, the COVID-19 pandemic had a significant impact on this study. While adaptations were made to continue recruitment and delivery of intervention therapy there was a period of time where the study had to be completely suspended due to the evolving health emergency and public health guidelines. During the same time period both the Health Service Executive and the University of Galway were targets of a cyber-attack which further interrupted recruitment processes and communication with clinical colleagues. As a consequence, data cannot be used to predict future recruitment patterns for replication. Also, feasibility indicators of therapy adherence, fidelity and resources outlined in the study protocol were not investigated given the sporadic nature of data collection. The mixed-modal delivery of assessment and intervention also requires further in-depth research in terms of validity, reliability, and fidelity beyond the scope of this study.

The assessment battery employed in this study was also deemed feasible in terms of delivery and acceptability to participants. In recent years, there has been a notable shift from a focus on symptom remission to a wider definition of recovery. Lally et al. (2017) helpfully distinguish between remission and recovery referring to remission as symptomatic and/or functional improvement over a >6-month time frame and using specific assessment criteria (The Remission in Schizophrenia Working Group RSWG criteria). Recovery is referred to as a multidimensional concept which encompasses symptomatic and functional improvement in social, occupational and educational domains over a time frame of >2 years (Lally et al., 2017). In this meta-analysis of long-term outcome studies of first episode of psychosis 58%

of participants met remission criteria at a mean of 5 years and 38% met recovery criteria at a mean of 7.2 years.

Slade et al., (2011) identify key elements of recovery from an individual perspective as connectedness, hope, identity, empowerment and having a meaningful role. However, these concepts are difficult to interpret and quantify at a service level and so may get 'lost in translation' using conventional outcome measures, such as hospital admission rates, symptom reduction or global level of functioning, in EIP research.

Therefore, it is acknowledged the measurement of social and occupational function and social cognition in the early psychosis cohort, and indeed across psychosis spectrum disorders, is not without its complexity (Pinkham et al., 2016;Long et al., 2022).Crude measures of function e.g., not in employment, education or training (NEET) status may merely capture a fleeting snapshot of function and general measures of function such as the Global Assessment Scale (GAF) have been critiqued for reflecting changes in symptomology rather than social function or social cognition (Robertson et al., 2013). In this study, we used the Time Use Survey (Hodgekins et al., 2015) in an attempt to more sensitively track changes in social and occupational function. Again, public health guidelines, lockdowns and restrictions, as a result of the COVID-19 pandemic, meant an accurate portrayal of typical time use and functional status could not be obtained.

Estimating treatment effect was not the primary aim of this randomised pilot study due to a pragmatic focus on feasibility for future definitive trials and being under powered to detect meaningful change. We however sought to explore change between the intervention and control groups and found no significant difference in primary and secondary outcomes. There were no significant demographic differences between intervention and control groups at baseline with the exception of the intervention group reporting significantly more hospitilisations than the control group (at a group level).A higher than expected FIQ for both the control and intervention groups was also noted.

When analysing within-intervention-group changes from baseline to post-intervention assessment, significant change in the primary outcome measure (SOFAS) was observed and this functional improvement appeared to be maintained at the final 3-month assessment time point. A similar pattern of improvement was noted for symptoms, with the exception of negative symptoms. Negative symptoms appeared to have a delayed or lagged response to treatment with significant improvement from post-intervention to 3-month follow up noted.

Only one social cognition measure demonstrated significant improvement from baseline to post-intervention, which was maintained at the final follow up assessment (The BLERT). These results are to be interpreted cautiously in the context of the sample size of this study.

Despite the challenges and limitations already described, the CReSt-R study was successful in terms of trialing the study protocol and exploring feasibility indicators and progression criteria. The intervention was acceptable to young people with early psychosis being described as meaningful, helpful, and engaging. The novelty of the intervention and its potential contribution to a multi-component model of care in early psychosis is a strength of this study. Preliminary data provided by this study along with participant and clinician feedback warrants progression to further feasibility research in EIP services. Prioritisation and further development of public patient involvement (PPI), beyond a consultation level, in the design and implementation of future studies is also recommended.

4.6 References

Addington, J., Saeedi, H., & Addington, D. (2006). Facial affect recognition: a mediator between cognitive and social functioning in psychosis?. *Schizophrenia research*, *85*(1-3), 142–150. https://doi.org/10.1016/j.schres.2006.03.028

Baron-Cohen, S., Wheelwright, S., Hill, J., Raste, Y., & Plumb, I. (2001). The "Reading the Mind in the Eyes" Test revised version: a study with normal adults, and adults with Asperger syndrome or high-functioning autism. *Journal of child psychology and psychiatry, and allied disciplines*, *42*(2), 241–251.

Bora, E., Eryavuz, A., Kayahan, B., Sungu, G., & Veznedaroglu, B. (2006). Social functioning, theory of mind and neurocognition in outpatients with schizophrenia; mental state decoding may be a better predictor of social functioning than mental state reasoning. *Psychiatry research*, *145*(2-3), 95–103. https://doi.org/10.1016/j.psychres.2005.11.003

Browne R. H. (1995). On the use of a pilot sample for sample size determination. *Statistics in medicine*, *14*(17), 1933–1940. https://doi.org/10.1002/sim.4780141709

Bryson, G., Bell, M., & Lysaker, P. (1997). Affect recognition in schizophrenia: a function of global impairment or a specific cognitive deficit. *Psychiatry research*, *71*(2), 105–113. https://doi.org/10.1016/s0165-1781(97)00050-4

Cacioppo, J. T., Petty, R. E., & Kao, C. F. (1984). The efficient assessment of need for cognition. *Journal of personality assessment*, *48*(3), 306–307. https://doi.org/10.1207/s15327752jpa4803_13

Choi, J., Mogami, T., & Medalia, A. (2010). Intrinsic motivation inventory: an adapted measure for schizophrenia research. *Schizophrenia bulletin*, *36*(5), 966–976. https://doi.org/10.1093/schbul/sbp030

Corcoran, R., Mercer, G., & Frith, C. D. (1995). Schizophrenia, symptomatology and social inference: investigating "theory of mind" in people with schizophrenia. *Schizophrenia research*, *17*(1), 5–13. https://doi.org/10.1016/0920-9964(95)00024-g

Correll, C. U., Galling, B., Pawar, A., Krikko, A., Bonetto, C., Ruggeri, M., Craig, T. J., Nordentoft, M., Srihari, V. H., Guloksuz, S., Hui, C., Chen, E., Valencia, M., Juarez, F., Robinson, D. G., Schooler, N. R., Brunette, M. F., Mueser, K. T., Rosenheck, R. A., Marcy, P., … Kane, J. M. (2018). Comparison of Early Intervention Services vs Treatment as Usual for Early-Phase Psychosis: A Systematic Review, Meta-analysis, and Meta-regression. *JAMA psychiatry*, 75(6), 555–565. https://doi.org/10.1001/jamapsychiatry.2018.0623

Cowman, M., Holleran, L., Lonergan, E., O'Connor, K., Birchwood, M., & Donohoe, G. (2021). Cognitive Predictors of Social and Occupational Functioning in Early Psychosis: A Systematic Review and Meta-analysis of Cross-Sectional and Longitudinal Data. *Schizophrenia bulletin*, *47*(5), 1243–1253. https://doi.org/10.1093/schbul/sbab033

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., Petticrew, M., & Medical Research Council Guidance. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ (Clinical research ed.)*, *337*, a1655. https://doi.org/10.1136/bmj.a1655

Donohoe, G., Dillon, R., Hargreaves, A., Mothersill, O., Castorina, M., Furey, E., … Robertson, I. H. (2018). Effectiveness of a low support, remotely accessible, cognitive

remediation training programme for chronic psychosis: cognitive, functional and cortical outcomes from a single blind randomised controlled trial. *Psychological Medicine*, 48(5), 751–764. http://doi.org/10.1017/S0033291717001982

Eldridge, S. M., Chan, C. L., Campbell, M. J., Bond, C. M., Hopewell, S., Thabane, L., Lancaster, G. A., & PAFS consensus group. (2016). CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ (Clinical research ed.)*, 355, i5239. https://doi.org/10.1136/bmj.i5239

Faul, F., Erdfelder, E., Lang, A.-G. & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behavior Research Methods, 39, 175-191.

Fett, A. K., Viechtbauer,W., Dominguez, M. D., Penn, D. L., van Os, J., & Krabbendam, L. (2011). The relationship between neurocognition and social cognition with functional outcomes in schizophrenia: a meta-analysis. *Neuroscience and biobehavioral reviews*, *35*(3), 573–588. https://doi.org/10.1016/j.neubiorev.2010.07.001

Fiszdon, J. M., & Reddy, L. F. (2012). Review of social cognitive treatments for psychosis. *Clinical psychology review*, *32*(8), 724–740. https://doi.org/10.1016/j.cpr.2012.09.003

Fowler, D., Hodgekins, J., Painter, M., Reilly, T., Crane, C., Macmillan, I., Mugford, M., Croudace, T., & Jones, P. B. (2009). Cognitive behaviour therapy for improving social recovery in psychosis: a report from the ISREP MRC Trial Platform Study (Improving Social Recovery in Early Psychosis). *Psychological medicine*, *39*(10), 1627–1636. https://doi.org/10.1017/S0033291709005467

Fowler, D., French, P., Hodgekins, J., Lower, R., Turner, R., Burton, S. & Wilson, J. (2013). CBT to Address and Prevent Social Disability in Early and Emerging Psychosis. In CBT for Schizophrenia, C. Steel (Ed.). https://doi.org/10.1002/9781118330029.ch8

Fowler, D., Hodgekins, J., French, P., Marshall, M., Freemantle, N., & McCrone, P. et al. (2018). Social recovery therapy in combination with early intervention services for enhancement of social recovery in patients with first-episode psychosis (SUPEREDEN3): a single-blind, randomised controlled trial. The Lancet Psychiatry, 5(1), 41-50. https://doi.org/10.1016/s2215-0366(17)30476-5

Fowler,D., Hodgekins,j.,Berry,C.,Clarke,T.,Palmier-Claus,J.,Sacadura c.,Graham,A.,Lowen,C.,Steele,A.,Pugh,K.,Fraser,S.,Fitzsimmons,M., & Paul French. (2019). Social recovery therapy: a treatment manual. *Psychosis*, 11:3, 261-272, https://doi.org/10.1080/17522439.2019.1607891

Frawley, E., Cowman, M., Cella, M., Cohen, D., Ryan, E., & Hallahan, B. et al. (2022). Cognitive Remediation and Social Recovery in Early Psychosis (CReSt-R): protocol for a pilot randomised controlled study. *Pilot And Feasibility Studies*, 8(1). https://doi.org/10.1186/s40814-022-01064-6

Green, M. F., & Horan, W. P. (2010). Social Cognition in Schizophrenia. *Current Directions in Psychological Science*, 19(4), 243–248. https://doi.org/10.1177/0963721410377600

Hodgekins, J., French, P., Birchwood, M., Mugford, M., Christopher, R., Marshall, M., Everard, L., Lester, H., Jones, P., Amos, T., Singh, S., Sharma, V., Morrison, A. P., &

Horan, W. P., Kern, R. S., Shokat-Fadai, K., Sergi, M. J., Wynn, J. K., & Green, M. F. (2009). Social cognitive skills training in schizophrenia: an initial efficacy study of stabilized outpatients. *Schizophrenia research*, *107*(1), 47–54. https://doi.org/10.1016/j.schres.2008.09.006

Hodgekins, J., French, P., Birchwood, M., Mugford, M., Christopher, R., Marshall, M., Everard, L., Lester, H., Jones, P., Amos, T., Singh, S., Sharma, V., Morrison, A. P., & Fowler, D. (2015). Comparing time use in individuals at different stages of psychosis and a non-clinical comparison group. *Schizophrenia research*, *161*(2-3), 188–193. https://doi.org/10.1016/j.schres.2014.12.011

Horan, W. P., & Green, M. F. (2019). Treatment of social cognition in schizophrenia: Current status and future directions. *Schizophrenia research*, *203*, 3–11. https://doi.org/10.1016/j.schres.2017.07.013

Kane, J. M., Robinson, D. G., Schooler, N. R., Mueser, K. T., Penn, D. L., Rosenheck, R. A., Addington, J., Brunette, M. F., Correll, C. U., Estroff, S. E., Marcy, P., Robinson, J., Meyer-Kalos, P. S., Gottlieb, J. D., Glynn, S. M., Lynde, D. W., Pipes, R., Kurian, B. T., Miller, A. L., Azrin, S. T., … Heinssen, R. K. (2016). Comprehensive Versus Usual Community Care for First-Episode Psychosis: 2-Year Outcomes from the NIMH RAISE Early Treatment Program. *The American journal of psychiatry*, 173(4), 362–372. https://doi.org/10.1176/appi.ajp.2015.15050632

Kay, S. R., Fiszbein, A., & Opler, L. A. (1987). The positive and negative syndrome scale (PANSS) for schizophrenia. *Schizophrenia bulletin*, *13*(2), 261–276. https://doi.org/10.1093/schbul/13.2.261

Kurtz, M. M., Gagen, E., Rocha, N. B., Machado, S., & Penn, D. L. (2016). Comprehensive treatments for social cognitive deficits in schizophrenia: A critical review and effect-size analysis of controlled studies. *Clinical psychology review*, *43*, 80–89. https://doi.org/10.1016/j.cpr.2015.09.003

Lakens, D. (2022). Sample Size Justification. *Collabra: Psychology* (1): 33267 https://doi.org/10.1525/collabra.33267

Lally, J., Ajnakina, O., Stubbs, B., Cullinane, M., Murphy, K., Gaughran, F., & Murray, R. (2017). Remission and recovery from first-episode psychosis in adults: A systematic review and meta-analysis of long-term outcome studies. *European Psychiatry*, *41*, S819. doi: 10.1016/j.eurpsy.2017.01.1595

Lancaster, G. A., Dodd, S., & Williamson, P. R. (2004). Design and analysis of pilot studies: Recommendations for good practice. *Journal of Evaluation in Clinical Practice*, *10*(2), 307–312. https://doi.org/10.1111/j..2002.384.doc.x

Leon, A. C., Davis, L. L., & Kraemer, H. C. (2011). The role and interpretation of pilot studies in clinical research. *Journal of Psychiatric Research*, 45(5), 626–629. https://doi.org/10.1016/j.jpsychires.2010.10.008

Long, M., Stansfeld, J. L., Davies, N., Crellin, N. E., & Moncrieff, J. (2022). A systematic review of social functioning outcome measures in schizophrenia with a focus on suitability for intervention research. *Schizophrenia research*, *241*, 275–291. https://doi.org/10.1016/j.schres.2022.02.011

McGlade, N., Behan, C., Hayden, J., O'Donoghue, T., Peel, R., Haq, F., Gill, M., Corvin, A., O'Callaghan, E., & Donohoe, G. (2008). Mental state decoding v. mental state reasoning as a mediator between cognitive and social function in psychosis. *The British journal of psychiatry : the journal of mental science*, *193*(1), 77–78. https://doi.org/10.1192/bjp.bp.107.044198

National institute for Health and Care Excellence (NICE). (2014). Psychosis and Schizophrenia in Adults: Prevention and Management, National Clinical Practice Guidelines (CG178). Retrieved from https://www.nice. org.uk/guidance/cg178/evidence/full-guideline-490503565.

National institute for Health and Care Excellence (NICE). (2015). Quality Standards for Mental Health Early Intervention Service Provision for Adults with Psychosis or Schizophrenia. Retrieved from https://www.nice. org.uk/guidance/qs80.

O'Donnell, C., Donohoe, G., Sharkey, L., Owens, N., Migone, M., Harries, R., Kinsella, A., Larkin, C., & O'Callaghan, E. (2003). Compliance therapy: a randomised controlled trial in schizophrenia. *BMJ (Clinical research ed.)*, *327*(7419), 834. https://doi.org/10.1136/bmj.327.7419.834

Osterrieth, P. A. (1944). Le Test du copie d'une figure complexe/ Test of coping a complex figure; Contribution to the study of perception and memory. *Archives of Psychology*,*30*, 206–356.

Pinkham, A. E., Penn, D. L., Green, M. F., Buck, B., Healey, K., & Harvey, P. D. (2014). The social cognition psychometric evaluation study: results of the expert survey and RAND panel. *Schizophrenia bulletin*, *40*(4), 813–823. https://doi.org/10.1093/schbul/sbt081

Pinkham, A. E., Penn, D. L., Green, M. F., & Harvey, P. D. (2016). Social Cognition Psychometric Evaluation: Results of the Initial Psychometric Study. *Schizophrenia bulletin*, *42*(2), 494–504. https://doi.org/10.1093/schbul/sbv056

Pinkham, A., Penn, D., & Harvey, P. (2018). M36. Social Cognition Psychometric Evaluation (SCOPE): Results: Of the Final Validation Study. *Schizophrenia Bulletin*, *43*(suppl_1), S224-S225. doi: 10.1093/schbul/sbx022.035

Reeder, C., Huddy, V., Cella, M., Taylor, R., Greenwood, K., Landau, S., & Wykes, T. (2017). A new generation computerised metacognitive cognitive remediation programme for schizophrenia (CIRCuiTS): a randomised controlled trial. Psychological Medicine, 47(15), 2720-2730. https://doi.org /10.1017/s0033291717001234

Robertson, D. A., Hargreaves, A., Kelleher, E. B., Morris, D., Gill, M., Corvin, A., & Donohoe, G. (2013). Social dysfunction in schizophrenia: an investigation of the GAF scale's sensitivity to deficits in social cognition. *Schizophrenia research*, *146*(1-3), 363–365. https://doi.org/10.1016/j.schres.2013.01.016

Rybarczk, B. (2011). Social and Occupational functioning assessment scale (SOFAS). In *Encyclopaedia of Clinical Neuropsychology* (ed. J.Kreutzer, J. DeLuca, and B. Caplan). pp 2313-2313. Springer. New York.

Skivington, K., Matthews, L., Simpson, S. A., Craig, P., Baird, J., Blazeby, J. M., Boyd, K. A., Craig, N., French, D. P., McIntosh, E., Petticrew, M., Rycroft-Malone, J., White, M., & Moore, L. (2021). A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ (Clinical research ed.)*, *374*, n2061. https://doi.org/10.1136/bmj.n2061

Slade M, Bird V, Le Boutillier C, Williams J, McCrone P, Leamy M. (2011). REFOCUS Trial: protocol for a cluster randomised controlled trial of a pro-recovery intervention within community based mental health teams. *BMC Psychiatry,* 11:185

Stroop J.R. (1935). Studies of interference in serial verbal reactions. *Journal of Experimental Psychology* 18, 643–662.

Szymczynska, P., Walsh, S., Greenberg, L., & Priebe, S. (2017). Attrition in trials evaluating complex interventions for schizophrenia: Systematic review and meta-analysis. *Journal of psychiatric research*, *90*, 67–77. https://doi.org/10.1016/j.jpsychires.2017.02.009

The British Psychological Society. (2020). Guidelines on psychological assessment undertaken remotely. Retrieved from: https://cms.bps.org.uk/sites/default/files/2022-06/Psychological%20assessment%20undertaken%20remotely.pdf

Vita, A., Barlati, S., Ceraso, A., Deste, G., Nibbio, G., & Wykes, T. (2022). Acceptability of cognitive remediation for schizophrenia: a systematic review and meta-analysis of randomized controlled trials. *Psychological medicine*, 1–11. Advance online publication. https://doi.org/10.1017/S0033291722000319

Wechsler, D. (1998). Wechsler Memory Scale, 3rd edn. (WMS- III). The Psychological Corporation: New York.

Wechsler, D. (1999). Wechsler Abbreviated Scale of Intelligence. The Psychological Corporation: Harcourt Brace & Company: New York.

Chapter 5. Participant Perspectives on Cognitive Remediation and Social Recovery in Early Psychosis (CReSt-R): An acceptability study

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Word Count Abstract: 263

Word Count Text: 3476

Number of Figures: 1 (Thematic model)

Number of Appendices: 1 (Qualitative Interview Schedule)

Trial Registration: Cognitive Remediation & Social Recovery in Early Psychosis (CreSt-R): ClincialTrials.gov Identifier NCT04273685. Trial registered Feb 18th, 2020. Last updated October 28th, 2022.

Ethical approval: This study was approved by the Galway Clinical Research Ethics Committee, Merlin Park Hospital, Galway, Ireland (reference number C.A. 2182).

Funding: This work was funded by the Irish Health Research Board as part of the collaborative doctoral award in Youth Mental Health [YOULEAD] (HRB grant number:CDA-2018-001).

Availability of data and materials: The full protocol in addition to datasets and statistical code generated during the current study will be available from the corresponding author on reasonable request.

5.1 Abstract

Introduction: Psychosis spectrum disorders continue to rank highly among causes of disability. This has resulted in efforts to expand the range of treatment targets beyond symptom remission to include other recovery markers, including social and occupational function and quality of life. Although the efficacy of psychosocial interventions in early psychosis has been widely reported, the acceptability of these interventions is less well-known. This study explores the participant perspective on a novel, psychosocial intervention combining cognitive remediation and social recovery therapy.

Methods: We employed a qualitative research design, based on semi-structured interviews and reflexive thematic analysis. Six participants with early psychosis were recruited from the intervention arm of a randomised pilot study, three women and three men, aged between 22 and 27 years.

Results: Four themes were developed through the analytical process, namely, (1) a solid therapeutic foundation, (2) multi-directional flow of knowledge, (3) a tailored toolset, and (4) an individual pathway to recovery. Participants also provided pragmatic feedback about how to improve the delivery of the therapy assessments and intervention. Both the themes and pragmatic feedback are described.

Conclusions: People with early psychosis described the intervention as acceptable, engaging, helpful and person-centred, suggesting its potential role in a multicomponent therapy model of early intervention in psychosis services. Participants in this study also highlight the importance of an individualised approach to therapy, the vital role of the therapeutic relationship and the ecological validity and value of adopting an assertive outreach delivery, providing therapy outside a conventional clinic setting.

Keywords: Early Psychosis, Psychosocial Intervention, Social function, Occupational Function, Social Recovery, Cognitive Remediation, Acceptability, Feasibility

5.2 Introduction

Psychosis spectrum disorders continue to rank highly among causes of disability in people aged 18-to-30-years-old (World Health Organisation, 2017). Although anti-psychotic medications are effective in targeting clinical symptoms, less than half of all patients are able to achieve functional recovery (Green, 2016). Residual impairments, even after successful pharmacological intervention, have a significant impact on functioning and disability in those living with psychosis (Fett et al., 2011, Horan & Green, 2019). Targeted psychosocial treatments embedded in early intervention in psychosis (EIP) are associated with significant gains in function, particularly when provided as part of a multicomponent model of care as operationalised in EIP services (Frawley et al., 2021). Although studies reported a variety of outcomes of psychosocial intervention, data on the acceptability are underreported.

This qualitative study addresses this gap by exploring the acceptability of the Cognitive Remediation and Social Recovery in Early Psychosis (CReSt-R) intervention for participants taking part in a trial. Feedback from these participants can improve the trial and will be integral in further development of this multicomponent intervention to optimise clinical utility. Designing, implementing, and evaluating psychosocial interventions in early psychosis is complex and now encompasses additional components such as acceptability, cost-effectiveness, scalability, and transferability across contexts (Skivington et al., 2021). Engaging stakeholders is a core element with acceptability highlighted as a fundamental element in the design and reporting of feasibility trials (O'Cathain et al., 2015). Acceptability is defined as the perception that a given treatment, service or practice is agreeable, palatable, or satisfactory (Proctor et al., 2011).

The CReSt-R study investigates the feasibility of a novel, multicomponent intervention. This intervention combines cognitive remediation training (CRT) and social recovery therapy (SRT), delivered in a 10-session programme. Sessions were primarily delivered at a therapeutic space at the University of Galway campus, and other community locations dependent on participant preference (e.g. some participants opted to have sessions in their home or online). E.F. was the primary therapist with clinical supervision provided by G.D. Briefly, the CRT programme used in this study is the Computerised Interactive Remediation of Cognition-Training for Schizophrenia (CIRCuiTS). CIRCuiTS is a web-based CRT programme which targets metacognition, specifically strategy use, in addition to massed practice of cognitive functions (attention, memory, and executive functioning) and follows the protocol of a previous randomised controlled trial (Reeder et al., 2017).

The SRT component is a cognitive behavioural therapy intervention that focuses on addressing barriers to individuals interacting in their social environment, e.g. social anxiety. It is informed by cognitive behavioural theory and addresses individual goals. SRT also follows an established protocol (Fowler et al., 2009; Fowler et al., 2013; Fowler et al., 2019) and has been the subject of a randomised trial in its own right (Fowler et al, 2018).The individual therapy components, primary and secondary outcome measures, and key feasibility indicators are outlined in the study protocol (Frawley et al., 2022) and trial registry (ClincialTrials.gov Identifier NCT04273685).

Participants were recruited from the outpatient department of Galway University Hospital Adult Mental Health Service (AMHS) and Galway Child and Adolescent Mental Health Services (CAMHS). Inclusion criteria were broad in nature for this study with a pragmatic approach operationalised. Inclusion criteria included being aged between 16 and 35 years of

age, within the first 5 years of a diagnosed psychotic illness (based on time since first contact with a clinical service), community based, clinically stable and having the ability to give consent. Exclusion criteria were having a history of organic impairment, history of a head injury with loss of consciousness > 5-min duration and drug abuse in the preceding month. While all participants met the inclusion criterion of having early-stage psychosis, there is currently no specialist early intervention in psychosis service available in this geographical location. Therefore, treatment as usual varied across participants.

In summary, participants received a ten-week therapy intervention with assessments completed at three time points throughout the study- at baseline prior to beginning the intervention, two weeks post-intervention and a follow-up time point at three months post-intervention. The purpose of this qualitative study is to explore the acceptability of the combined, multicomponent intervention to people aged 16-35 years in the early psychosis population.

5.3 Method

An interview schedule was developed with a focus on eliciting participant feedback on: their general experience of participating in the intervention, intervention components, mechanisms of change, communication with the research therapist, experience of assessment sessions, and perceived benefits and challenges of participating in the intervention (see supplementary material).The interview schedule builds upon previous acceptability studies of each therapy component (Reeder et al., 2016; Gee et al., 2018) with additional emphasis on people's experience of the bridging of therapies, and general experience of participating in the trial. There was no public patient involvement (PPI), reflecting lived and living experience perspectives, in the design of the study and interview schedule. This is acknowledged as a limitation of the study in the discussion below.

Participants were recruited through purposive sampling of the intervention arm of the randomised pilot study. All intervention participants (sixteen in total: those who completed the therapy protocol (13) and those who left therapy early (3)) were invited to participate in the qualitative study via email with information regarding the purpose of the qualitative study, data management, and the format of the planned semi-structured interviews. Of the sixteen invitees, five declined to participate for a variety of reasons e.g., some participants did not want to be recorded, others cited other personal time demands such as study and work commitments as barriers to participation. Five invitees did not respond to the invite.

In total, six participants consented to participate: three women and three men aged between 22 and 27 years. All six participants completed the intervention protocol in its entirety, including the ten-week therapy intervention, baseline assessment, and two follow-up assessment sessions. All participants were within the first five years of a diagnosed psychotic disorder and were not receiving other psychosocial intervention at the time of the study. Participants opted in and provided written consent via responding to the email and were contacted by a member of the research team (E.F.) to schedule an interview date thereafter. In-depth semi-structured interviews were completed online via a secure platform with a member of the research team not directly involved in delivery of the intervention (G.D.). Interviews, undertaken from July to November 2021, varied in duration from 40-60 minutes (*Mdn* = 44, *range* = 20). All interviews were recorded and transcribed verbatim. Transcribed interviews were uploaded to NVivo software (released in March 2020) for analysis.

A reflexive thematic analysis was undertaken (Braun & Clarke, 2006; Braun & Clarke, 2022; Notley et al.,2014). A reflexive approach to thematic analysis was used, as opposed to alternative models such as coding reliability or codebook approaches to thematic analysis, due to the robust process guidelines and theoretical flexibility it offers (Braun & Clark, 2022;Byrne,2021).The process guidelines (six phases of reflexive thematic analysis) provided

a clear and efficient work plan for the research team to follow. The guidelines were followed in an iterative manner and not necessarily in a linear fashion as the data was explored, and codes and themes developed, reviewed, and refined. Fundamentally, the reflexive approach to thematic analysis also highlights the researcher's active role in knowledge production. In this regard, researcher subjectivity is seen as a primary tool in making meaning of the data set and the development of codes and themes (Braun & Clark,2022). Given the proximity of the researchers to the CReSt-R intervention, reflexivity and use of a reflexive journal was considered an advantage in adopting this approach and interpreting the data set.

When analysing the data, a critical realist epistemological approach was adopted, attempting to make meaning of participants' realities through exploring their perspectives and expressed language of their experiences (Danermark et al., 2002). Analysis involved deep familiarisation with the data in both aural and transcribed formats with ongoing, active reflection on both the content and process by the researchers. E.F. completed a reflexive journal throughout the research process. Coding of all transcripts was completed by E.F. NVivo software was used for efficiency of organising and visualising data and recording decision making processes for quality control purposes. Independent coding of a sample of transcripts was also undertaken by C.H. and C.B. Congruent with a reflexive thematic analysis approach, the aim was not to reach a consensus on coding, but rather to enrich the understanding and interpretation of the data and fuel discussion at coding meetings with E.F., C.H., C.B., and G.D. Themes were generated, reviewed, and developed in an iterative process.

5.4 Results

In general, the CReSt-R intervention was described as acceptable by the participants who took part in this qualitative study. They also stated they would recommend the intervention to others. The four themes developed during the reflexive thematic analysis traverse individual participant perspectives and interconnect to form a model of acceptability as conveyed in Figure 1.

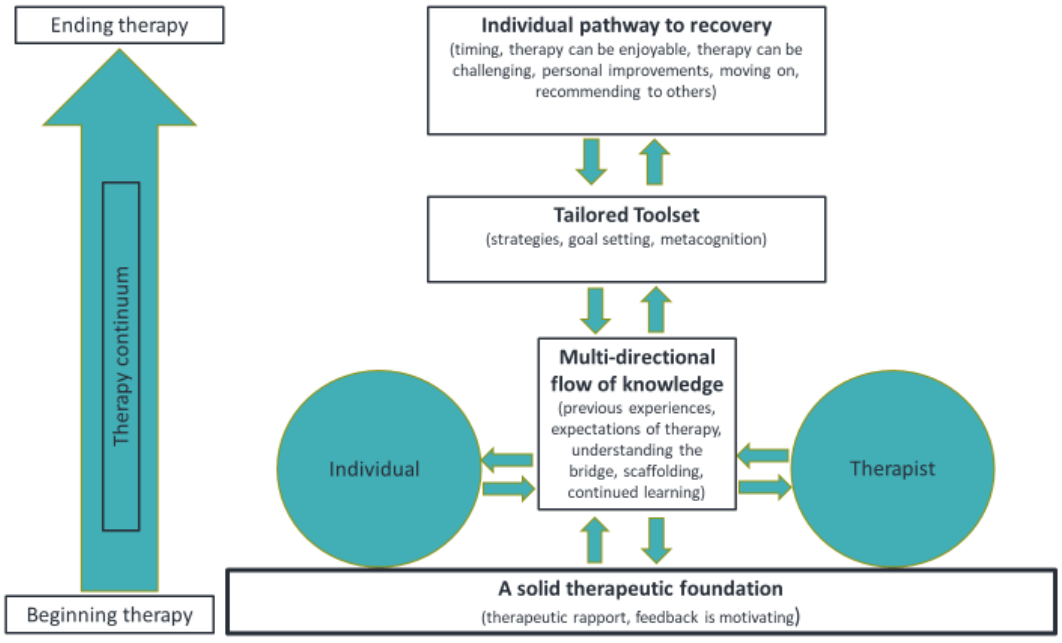
5.4.1 A solid therapeutic foundation

The relationship with the therapist was consistently described as central to the participants' experience of the intervention. This reflects findings from a recent paper highlighting facilitation by a therapist as a core feature of cognitive remediation training (Bowie et al., 2020). Participants described feeling apprehensive about taking part in the study; however, once they met the therapist and began to develop a rapport, this fostered a sense of security and promoted active engagement with the therapy process. Participants mentioned the value of feeling heard, active listening, and a sense of affirmation from the interactions in therapy sessions, as the following quote illustrates: *'But when I was talking, she was very good at helping me to express myself. You know when I'd say something she'd nod her head and smile at me, and that sort of affirmation was very helpful for me that I knew that she was taking everything in and listening and that what I was saying was relevant' (woman, aged 26)*

The continuity of therapy sessions (a regular meeting time, regular and predictable contact from the therapist and a regular meeting place) was also described as a source of reassurance and support in the context of individual recovery. Participants described a sense of safety in terms of the cognitive and emotional demands of therapy and also in the physical space, outside a conventional clinic setting. Having a regular meeting time and receiving ongoing

feedback from the therapist was described as a source of extrinsic motivation. This therapeutic relationship was described as forming a solid foundation from which the therapy process could develop and was fundamental in the perception of acceptability of the intervention. The structure of the intervention, combining cognitive remediation training and social recovery therapy, allowed continuity of feedback to the young person. Selection of goals, strategies, space to reflect on cognitive strengths and challenges and progress made towards collaborative goals were described by participants as strengths of the intervention: *'It was very structured you know and I suppose we could see as the weeks went on how well I was doing in it and how I was improving and that kind of thing. So that was helpful' (man, aged 26).*

Figure 5.1. Thematic model of CReSt-R Acceptability



5.4.2 Multi-directional flow of knowledge

Central to the acceptability of the intervention was the transfer of knowledge between participant and therapist. Participants described sharing their previous experiences with

mental health services, fears, and expectations of therapy: '*Yeah, I suppose I was afraid that you know the therapist would be disappointed with me that I wouldn't talk enough. And I was also afraid that I might be put under pressure to think positively or do things that I felt were overwhelming' (woman, aged 26).* This allowed for an open discussion on how they may best be supported throughout the therapeutic process: *'If it wasn't flexible, I don't think I would have been able to do it, or if it was too intensive' (woman, aged 22). 'I need help with understanding information, I find it kind of overwhelming. I need space and a bit of time for it to soak in' (man, aged 23).*

This shared knowledge was described as strengthening the therapeutic relationship and was pivotal in creating a flow of knowledge. This flow of knowledge was not only between participant and therapist but also intrinsic to the individual participant, allowing for self-reflection and development of self-awareness: *'We did a mind map looking at my behaviours in the centre of it and my thoughts and emotions and that. I found it very helpful that sometimes she'd put words on things and other times she got me to put words on the things and it emerged that one of my behaviours was avoidance that I was avoiding meeting people and talking to people. And just to identify that behaviour was very clarifying for me and then we could begin to challenge it a bit' (woman, aged 22).*

This multi-directional flow of knowledge was described as empowering in terms of informing collaborative goals, selection and application of therapy strategies and the focus of individual therapy sessions in the context of individual recovery and developing a 'toolset' to reach their goals: *'I know that my values and goals have changed since the study. It did help me gain like confidence in kickstarting or like springboard into what I'm kind of doing now, to take the next steps myself '(woman, aged 22).*

5.4.3 A tailored toolset

Participants described being experts in their own lived experience and recovery, contributing to a collaborative formulation whilst also describing the therapist as a source of knowledge, feedback, and affirmation. Participants also described a sense of individualism and autonomy in the therapy intervention. Rather than a 'one size fits all' approach, they were active agents in guiding the sessions and focus of therapy: *'Yeah my sessions now would be completely different to another person's you know what I mean, it was tailored to me, it was spot on' (man, aged 27). 'We were setting goals as to what I wanted to do in the future and stuff like that you know, goals important for me, stuff I have control over' (woman, aged 26).*

Goal setting and strategy use were highlighted by participants as strengths of the intervention. Whilst setting goals was an important source of motivation for participants, it was also described as a challenging process: '*Initially I was sceptical and I thought you know we'll set goals and I'll never be able to reach them. But as we went on through the therapy, I was able to see you know it clarifies in your mind you know what you're trying to do and then you can begin to work it out and do something about it. And I feel like my goals were reached quite well at the end of the therapy so I was happy about that' (man, aged 26).*

'A strategy that stands out is writing things down, that I'd remember things better if I write them down. And I suppose even writing things down just to express myself as well and reduce anxiety I've still used that since the therapy. That would be the main thing' (woman aged 22).

Thinking about thinking or metacognition were used interchangeably by participants to describe both therapy components and how this was tailored to them. They described developing an awareness of their cognitive strengths and challenges and working alongside the therapist to identify strategies specific to their daily life and selected goals. Similar to goal setting, metacognition was also described as a concept that was challenging to articulate at

first, however, one they became familiar with by the end of the intervention: *'I'd describe it as becoming more aware of your thoughts and emotions and learning how to challenge your thinking. Yeah being able to manage on your own with thoughts and emotions a bit better and reduce your anxiety levels' (woman, aged 22).*

The sense of tailoring the intervention to meet individual needs was described as appealing to participants, again strengthening engagement, and facilitating a flow of knowledge that allowed them to *'try out'* strategies in *'real life'* and discuss these experiences in the safety of the therapy intervention. This tailored toolset traversed both therapy intervention components (CRT and SRT).

5.4.4 An individual pathway to recovery

All participants interviewed stated they would recommend the intervention to others. However, participants highlighted the importance of the timing of the intervention and proximity to an acute episode of psychosis and where an individual may be on their personal recovery journey. This provides an interesting perspective on when to offer this intervention to participants: *'I suppose I think every individual has a different journey to make. And if the program had been offered to me a year ago, I probably wouldn't have even gone on it. So it depends on the frame of mind that you're in to be even open to the program. It just got me at a very good time' (woman, aged 26).*

While feedback on the intervention was positive, participants did describe both enjoyable and challenging aspects, again each perspective was unique to the young person in the context of their individual pathway to recovery. Participants particularly reported at times finding the at-home cognitive remediation training component as challenging without the external motivation and feedback from the therapist: *'I suppose I found it difficult sometimes to complete the circuits every week you know and it got a bit repetitive at times. So that would*

have been one thing that might have needed changed' (man, aged 23). This varied between participants, suggesting that support for at-home cognitive remediation training should be tailored to the individual and integrated into individual recovery plans.

All participants reported personal improvements or achieved goals at the end of the therapy intervention. Whilst not all goals were met, the process of setting goals was described as something which could be carried forward to future endeavours: *'I've achieved the goals like the long-term goals. I was talking a lot about trying to get back into work and I'm working now. And I was talking about moving out and I've moved out of the home house so now I'm in the town. So the goals actually came around full circle you know' (man, aged 26).*

The ending of therapy was described by participants as both a positive and challenging experience. Whilst progress towards goals was described, there was a natural sense of uncertainty but also hopefulness about the next step, independent of therapy sessions: *'And the therapy had basically given me the way to not because I'm not looking at myself so negatively or I'm not looking at my life as being unmanageable that I can take the progress you know towards making these steps and having the confidence to do so (woman, aged 26).*

5.4.5 Pragmatic feedback

Study participants also provided feedback on the delivery of the multicomponent intervention and experience of assessments completed at three time points. While this pragmatic feedback is not included in the thematic model of acceptability (Figure 1), it is included to provide additional context to the individual experience of the therapy process. The therapy intervention was delivered both in-person and online during the COVID-19 pandemic. All participants stated online sessions were acceptable, however, there was a consensus that in-person sessions (for assessment and therapy) were preferrable: *'I preferred in-person ones better when you're talking about kind of personal things to do with being personal' (man,*

aged 27). Participants also stated a preference for therapy to be held outside of a traditional clinic setting, e.g. on a university campus or other community location: *'Hospitals I don't particularly like. Yeah I just find it's easier to focus in a different setting' (woman, aged 22).*

Two of the six participants stated they would have preferred if the therapy intervention lasted longer than ten weeks, whilst the remaining participants were satisfied with the duration of the intervention in its current form. Regardless of duration, receiving feedback, planning for after therapy and being kept up to date with study progress were highlighted as important by all participants.

Assessment sessions were described as quite long and challenging with participants describing the need to split the assessment sessions in two. Participants described the assessments as abstract and were unsure if the outcomes used captured the progress they made in therapy: *'But I thought maybe the clinical assessment focused an awful lot on sort of abstract things like what we'd cover in circuits and that. and there were a few questions about mood and maybe sort of different activities I might do but I'm not sure that it fully captured the progress I had made. Maybe if there were more questions around how you feel around other people or you know how your interactions with other people have changed it might capture the progress a bit better' (woman, aged 26).*

It was also apparent from participant interviews that more detailed information about the intervention at the point of recruitment may be beneficial for participants. Also, further emphasis on the rationale for both therapy components and the bridge between the two components should be considered in future intervention delivery with some ambivalence described: *'Maybe if there was a better link between circuits and the cognitive behavioural therapy if I could see more of a connection between the two….well I mean it made sense that they were together. Like kind of the goal to recover from psychosis and cognition is a big part*

of that and CBT is a big part of that too so I presume yeah they did kind of. They were very different but they did work for what they did. Yeah they worked' (man, aged 27).

5.5 Discussion/Conclusions

In summary, this qualitative study indicated that the specific intervention assessed was broadly acceptable to those who took part in the study. More generally, the acceptability model developed as part of the data analysis has the potential for transferability to other therapies in this cohort. The participants with psychosis interviewed here particularly described goal setting, selection of strategies that may be applied to everyday life, and the concept of 'thinking about thinking' or metacognition as core elements of the combined intervention they found helpful and engaging. It was especially important that these core elements were tailored to the young person in the context of their individual recovery. From a clinical perspective, this can also be considered in the context of a clinical staging model (McGorry et al., 2007), highlighting the significance of when, and to whom this type of intervention is offered.

The foundation upon which the intervention sits is the therapeutic relationship and a sense of being seen, heard, involved, and valued in the therapy process, allowed for a multi-directional flow of knowledge between the young person and the therapist. The importance of the presence of an active and trained therapist has previously been identified as a core element of CRT (Bowie et al., 2020), demonstrating a positive impact on cognitive outcomes, but not on a proxy of acceptability namely drop-out rates (Vita et al, 2021; Vita et al 2022). The importance of the therapeutic relationship in the combined therapy intervention was highlighted by the people in this study.

A limitation of this study is that the research team were unable to recruit any participants who left the trial early. Three participants left the trial before session five, when social recovery therapy begins. Feedback from these participants at the point of leaving the study was that they felt not ready for 'this type of therapy'; this feedback reflected the theme of the individual pathway to recovery and individual timing of when an intervention such as this is appropriate for and acceptable to a young person. It also emphasises the feedback from participants to strengthen the *'bridge'* between the two therapy components. Some found it difficult to make the connection between CIRCuiTS and their social recovery, without the extrinsic support from the therapist. This is an important consideration for future therapy delivery. The drop-out rate will be considered as a proxy of acceptability along with the findings of this qualitative study in the overall feasibility trial.

Participants emphasised a preference for in-person therapy sessions, specifically located in the community, outside conventional clinic settings. They describe this as important in promoting active engagement with the intervention. Feedback on mode of delivery of the intervention will be integrated with other feasibility considerations for implementation of the intervention in the future.

Sample size for this qualitative study, embedded in the context of a randomised pilot study, is congruent with a reflexive thematic analysis approach with data viewed through a lens of richness rather than saturation (Braun & Clarke, 2019) Vasileiou et al. (2018) caution against decontextualised sample size numerical guidelines in qualitative research but rather emphasise the context of the individual study itself. We highlight the proximity of the participants to the CReSt-R intervention and the richness of their described experiences in providing invaluable insights to the acceptability and feasibility of the intervention.

This qualitative study provides important data for further developing the CReSt-R intervention. Acceptability themes described by participants in this study are a solid therapeutic foundation; knowledge exchange between the young person and therapist; consideration of the timing of this intervention for a young person in their recovery process; and the importance of active, autonomous therapy 'tools' to promote individual engagement and recovery. Pragmatic feedback also highlights the importance of reviewing the setting and duration of the therapy intervention and assessment sessions in a future definitive trial. Development of public patient involvement (PPI) in the design, delivery, analysis and dissemination of future qualitative studies of the intervention is also highlighted as a priority by the authors.

Early intervention in psychosis (EIP) is recognised as providing multicomponent, targeted interventions that benefit individuals living with psychosis in terms of remission, recovery, and functional trajectory (Hodgekins et al., 2015; Kane et al., 2016; Corell et al.,2018). Current clinical guidelines focus on the provision of pharmacological intervention in conjunction with several specific psychosocial interventions (namely, cognitive behavioural therapy for psychosis (CBTp), family-based interventions and supported employment) (National Institute for Health and Care Excellence (NICE), 2014,2015). Despite this, however, impairment in cognitive performance persists, is not effectively targeted by current interventions, and continue to have a significant impact on function and the rate of disability in those living with psychosis (Fett et al., 2011; Horan & Green, 2019; Cowman et al, 2021). Given the evidence that cognitive and particularly social cognition may be relevant to improving social function, it is possible that better managing cognitive difficulties as part of psychosocial trials may result in improved effectiveness of psychosocial therapies.

For example, CBTp seeks to target dysfunctional beliefs by identifying and examining the evidence for and against those beliefs and replace faulty beliefs with more adaptive beliefs. Doing so is highly cognitively demanding, particularly when evidence gathering, and testing depends on social cognitive processes (e.g. attributing meaning to social interactions). Meeting the demands of a cognitively challenging intervention like CBTp has the potential to be greatly facilitated by also targeting cognitive function either alongside or as a prequel to

targeting clinical symptoms. The potential benefit of doing so would be to increase patients' abilities to engage in psychosocial intervention in the context of a multicomponent early intervention service. The CReSt-R study, in a feasibility stage, does not yet report on the efficacy of the intervention. This study however, reports from an acceptability perspective, an intervention that is described as not only acceptable but engaging, helpful and person-centred, and continues to suggest that it may have a potential role in a multicomponent therapy model in EIP.

5.6 References

Bowie, C. R., Bell, M. D., Fiszdon, J. M., Johannesen, J. K., Lindenmayer, J. P., McGurk, S. R., Medalia, A. A., Penadés, R., Saperstein, A. M., Twamley, E. W., Ueland, T., & Wykes, T. (2020). Cognitive remediation for schizophrenia: An expert working group white paper on core techniques. *Schizophrenia research*, *215*, 49–53. https://doi.org/10.1016/j.schres.2019.10.047

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research In Psychology*, 3(2), 77-101. https://doi.org/10.1191/1478088706qp063oa

Braun, V., & Clarke, V. (2019). To saturate or not to saturate? Questioning data saturation as a useful concept for thematic analysis and sample-size rationales. *Qualitative Research In Sport, Exercise And Health*, *13*(2), 201-216. https://doi.org/10.1080/2159676x.2019.1704846

Braun, V., & Clarke, V. (2022). *Thematic Analysis, A practical Guide.* London: SAGE publications.

Byrne, D. (2021). A worked example of Braun and Clarke's approach to reflexive thematic analysis. Quality & Quantity, 56(3), 1391-1412. doi:10.1007/s11135-021-01182-y

Correll, C. U., Galling, B., Pawar, A., Krivko, A., Bonetto, C., Ruggeri, M., Craig, T. J., Nordentoft, M., Srihari, V. H., Guloksuz, S., Hui, C., Chen, E., Valencia, M., Juarez, F., Robinson, D. G., Schooler, N. R., Brunette, M. F., Mueser, K. T., Rosenheck, R. A., Marcy, P., … Kane, J. M. (2018). Comparison of Early Intervention Services vs Treatment as Usual for Early-Phase Psychosis: A Systematic Review, Meta-analysis, and Meta-regression. *JAMA psychiatry*, 75(6), 555–565. https://doi.org/10.1001/jamapsychiatry.2018.0623

Cowman, M., Holleran, L., Lonergan, E., O'Connor, K., Birchwood, M., & Donohoe, G. (2021). Cognitive Predictors of Social and Occupational Functioning in Early Psychosis: A Systematic Review and Meta-analysis of Cross-Sectional and Longitudinal Data. *Schizophrenia bulletin*, *47*(5), 1243–1253. https://doi.org/10.1093/schbul/sbab033

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *British Medical Journal*, a1655. https://doi.org/10.1136/bmj.a1655

Danermark, B., Ekstrom, M., Jakobsen, L., Karlsson, JC. (2002) *Explaining Society – Critical Realism in the Social Sciences*. Routledge.

Fett, A., Viechtbauer, W., Dominguez, M., Penn, D., Van Os, J., & Krabbendam, L. (2011). The relationship between neurocognition and social cognition with functional outcomes in schizophrenia: A meta-analysis. *Neuroscience & Biobehavioral Reviews*, 35(3), 573-588. doi: 10.1016/j.neubiorev.2010.07.001

Fowler, D., Hodgekins, J., Painter, M., Reilly, T., Crane, C., & Macmillan, I. et al. (2009). Cognitive behaviour therapy for improving social recovery in psychosis: a report from the ISREP MRC Trial Platform study (Improving Social Recovery in Early Psychosis). *Psychological Medicine*, 39(10), 1627. https://doi.org/10.1017/s0033291709005467

Fowler D, French P, Hodgekins J, et al. (2013) CBT to address and prevent social disability in early and emerging psychosis. In: Steel C, ed. *CBT for schizophrenia: evidence-based interventions and future directions*: Oxford: John Wiley & Sons. 143-67

Fowler, D., Hodgekins, J., French, P., Marshall, M., Freemantle, N., & McCrone, P. et al. (2018). Social recovery therapy in combination with early intervention services for enhancement of social recovery in patients with first-episode psychosis (SUPEREDEN3): a single-blind, randomised controlled trial. The Lancet Psychiatry, 5(1), 41-50. https://doi.org/10.1016/s2215-0366(17)30476-5

Fowler, D., Hodgekins, J., Berry, C., Clarke, T., Palmier-Claus, J., Sacadura, C., Graham, A., Lowen, C., Steele, A., Pugh, K., Fraser, S., Fitzsimmons, M., & French, P. (2019). Social recovery therapy: A treatment manual. *Psychosis: Psychological, Social and Integrative Approaches*, 11(3), 261–272. https://doi.org/10.1080/17522439.2019.1607891

Frawley, E., Cowman, M., Lepage, M., & Donohoe, G. (2021). Social and occupational recovery in early psychosis: a systematic review and meta-analysis of psychosocial interventions. *Psychological Medicine*, 1–12. http://doi.org/10.1017/S003329172100341X

Frawley, E., Cowman, M., Cella, M., Cohen, D., Ryan, E., & Hallahan, B. et al. (2022). Cognitive Remediation and Social Recovery in Early Psychosis (CReSt-R): protocol for a pilot randomised controlled study. *Pilot And Feasibility Studies*, 8(1). https://doi.org/10.1186/s40814-022-01064-6

Gee, B., Notley, C., Byrne, R., Clarke, T., Hodgekins, J., French, P. and Fowler, D. (2018), Young people's experiences of Social Recovery Cognitive Behavioural Therapy and treatment as usual in the PRODIGY trial. *Early Intervention in Psychiatry*, 12: 879-885. https://doi.org/10.1111/eip.12381

Green, M. (2016). Impact of Cognitive and Social Cognitive Impairment on Functional Outcomes in Patients With Schizophrenia. *The Journal Of Clinical Psychiatry*, 77(Suppl 2), 8-11. doi: 10.4088/jcp.14074su1c.02

Hodgekins, J., Birchwood, M., Christopher, R., Marshall, M., Coker, S., Everard, L., . . . Fowler, D. (2015). Investigating trajectories of social recovery in individuals with first-episode psychosis: a latent class growth analysis. *British Journal of Psychiatry*, *207*(6), 536-543. doi:10.1192/bjp.bp.114.153486

Horan, W., & Green, M. (2019). Treatment of social cognition in schizophrenia: Current status and future directions. *Schizophrenia Research*, 203, 3-11. doi: 10.1016/j.schres.2017.07.013

Kane, J. M., Robinson, D. G., Schooler, N. R., Mueser, K. T., Penn, D. L., Rosenheck, R. A., Addington, J., Brunette, M. F., Correll, C. U., Estroff, S. E., Marcy, P., Robinson, J., Meyer-Kalos, P. S., Gottlieb, J. D., Glynn, S. M., Lynde, D. W., Pipes, R., Kurian, B. T., Miller, A. L., Azrin, S. T., … Heinssen, R. K. (2016). Comprehensive Versus Usual Community Care for First-Episode Psychosis: 2-Year Outcomes From the NIMH RAISE Early Treatment Program. *The American journal of psychiatry*, 173(4), 362–372. https://doi.org/10.1176/appi.ajp.2015.15050632

McGorry, P. D., Purcell, R., Hickie, I. B., Yung, A. R., Pantelis, C., & Jackson, H. J. (2007). Clinical staging: a heuristic model for psychiatry and youth mental health. *The Medical journal of Australia*, *187*(S7), S40–S42. https://doi.org/10.5694/j.1326-5377.2007.tb01335.x

National institute for Health and Care Excellence (NICE). (2014). Psychosis and Schizophrenia in Adults: Prevention and Management, National Clinical Practice Guidelines (CG178). Retrieved from https://www.nice. org.uk/guidance/cg178/evidence/full-guideline-490503565.

National institute for Health and Care Excellence (NICE). (2015). Quality Standards for Mental Health Early Intervention Service Provision for Adults with Psychosis or Schizophrenia. Retrieved from https://www.nice. org.uk/guidance/qs80.

Notley, C., Green, G., Maryland, L. (2014) Qualitative analysis. In: Walker DM, ed. *An Introduction to Health Services Research*. London: Sage Publications, 327–42. 13.

O'Cathain, A., Hoddinott, P., Lewin, S. et al. (2015) Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. *Pilot & Feasibility Studies* 1, 32. https://doi.org/10.1186/s40814-015-0026-y

Power, P., & Robinson, J. (2009) Suicide Prevention in First Episode Psychosis. In: The Recognition and Management of Early Psychosis: a Preventative Approach. Ed: Patrick McGorry, Alison Yung & Henry Jackson, pp 257-282, Cambridge University Press.

Proctor, E., Silmere, H., Raghavan, R., Hovmand, P., Aarons, G., & Bunger, A. et al. (2010). Outcomes for Implementation Research: Conceptual Distinctions, Measurement Challenges, and Research Agenda. Administration And Policy. *Mental Health And Mental Health Services Research*, 38(2), 65-76. https://doi.org/10.1007/s10488-010-0319-7

Reeder, C., & Wykes, T. (2010) Cognitive Interaction Remediation of Cognition - a Training for Schizophrenia (CIRCuiTS); King's College London: UK.

Reeder, C., Huddy, V., Cella, M., Taylor, R., Greenwood, K., Landau, S., & Wykes, T. (2017) A new generation computerised metacognitive cognitive remediation programme for schizophrenia (CIRCuiTS): a randomised controlled trial. *Psychological. Medicine*, 47(15): 2720-2730.

Reeder, C., Pile, V., Crawford, P., Cella, M., Rose, D., Wykes, T., . . . Callard, F. (2016). The Feasibility and Acceptability to Service Users of CIRCuiTS, a Computerized Cognitive Remediation Therapy Programme for Schizophrenia. *Behavioural and Cognitive Psychotherapy*, 44(3), 288-305. doi:10.1017/S1352465815000168

Skivington, K., Matthews, L., Simpson, S., Craig, P., Baird, J., & Blazeby, J. et al. (2021). A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *British Medical Journal*, n2061. https://doi.org/10.1136/bmj.n2061

Vasileiou, K., Barnett, J., Thorpe, S., & Young, T. (2018). Characterising and justifying sample size sufficiency in interview-based studies: systematic analysis of qualitative health research over a 15-year period. *BMC Medical Research Methodology*, *18*(1). https://doi.org/10.1186/s12874-018-0594-7

Vita A, Barlati S, Ceraso A, et al. Effectiveness, Core Elements, and Moderators of Response of Cognitive Remediation for Schizophrenia: A Systematic Review and Meta-analysis of Randomized Clinical Trials. *JAMA Psychiatry.* 2021;78(8):848–858. doi:10.1001/jamapsychiatry.2021.0620

Vita, A., Barlati, S., Ceraso, A., Deste, G., Nibbio, G., & Wykes, T. (2022). Acceptability of cognitive remediation for schizophrenia: a systematic review and meta-analysis of randomized controlled trials. *Psychological medicine,* 1–11. Advance online publication. https://doi.org/10.1017/S0033291722000319

World Health Organization.(WHO) Depression and other common mental disorders: Global Health Estimates. Geneva: World Health Organization; 2017

Chapter 6. General Discussion

6.1 Discussion Overview

This general discussion chapter will present a summary of the overall findings of this thesis. It will detail the contribution made by this research to the evidence base for psychosocial interventions in early psychosis and the feasibility and acceptability of developing and piloting a novel psychosocial intervention combining cognitive remediation training and social recovery therapy. The strengths and limitations of each study will be discussed along with implications of the findings for future research and practice. Finally, this chapter will conclude with reflections on the PhD process and the experience of participating in a collaborative doctoral award programme.

6.2 Summary of research findings

6.2.1 Study One

Study one presents the results of a systematic review and meta-analysis that focused on psychosocial intervention and functional outcomes in the high-risk and early psychosis cohorts. The 31 studies included were categorised as: cognitive behavioural therapy for psychosis (CBTp), family-based therapy, supported employment, cognitive remediation training (CRT) and multi-component psychosocial interventions, as described in the study methodology.

There was an insufficient number of supported employment and family-based intervention studies to calculate an effect size specific to those intervention categories; however the studies available were included in the overall analysis. Across all interventions, improved function was observed (SMD = 0.239; 95% confidence interval 0.115–0.364, $p < 0.001$). When non-randomised control trial studies (three studies in total) were excluded the effect size changed only marginally (SMD = 0.251). Multi-component interventions were associated with the largest gains in social and occupational function (SMD = 0.452, 95% CI

(0.061–0.843), p = 0.023). CRT was associated with modest but significant improvements in social and occupational function when compared to control conditions (SMD = 0.301, 95% CI (0.004–0.599), p = 0.047). CBTp interventions were not associated with significant changes on validated measures of social and occupational functioning (SMD = 0.139, 95% CI (−0.021 to 0.299), p = 0.089). Of note, five of eight studies in the CBTp group were of an at-risk cohort. Excluding these at-risk cohort studies, a significant change in function was observed post intervention across the remaining three studies (SMD = 0.345, p < 0.005), but the small sample size made it difficult to draw firm conclusions about these changes.

Sub-group analyses demonstrated that effect sizes varied by stage of illness, length and duration of intervention, study control condition, mode of intervention delivery and outcome measure used. Effect sizes were greater in the early psychosis cohort, interventions which were longer in duration, studies that used treatment as usual as a control condition rather than an active control, interventions that were community-based and in those studies which used more specific (rather than general) measures of function. Overall, study one, notwithstanding limitations which will be discussed below, provides exploratory evidence for the effectiveness of psychosocial intervention in improving social and occupational function in early psychosis.

6.2.2 Study two

Study two presents the research protocol for the *Cognitive Remediation and Social Recovery in Early Psychosis* (CReSt-R) study. This publication is a culmination of an in-depth consideration of existing cognitive remediation training and psychosocial therapies, trial methodologies, and collaboration with international experts that led to the development of the protocol. It describes the rationale for selecting the intervention components of the CIRCuiTS CRT programme and Social Recovery Therapy and outlines the design of the randomised, controlled, pilot study.

Study two describes the overall aim of the CReSt-R study to gather and analyse acceptability and feasibility data to (1) further develop and refine the novel, multi-component CReSt-R intervention (2) investigate the feasibility of delivering and evaluating the intervention in future definitive trials. Specifically, the study objectives include the following: (1) To collect qualitative and quantitative data to assess the feasibility of the intervention with indicators in

the areas of process, intervention, and resources. (2) To investigate if the CReSt-R intervention is acceptable to young people, aged 16–35, who are within the first 5 years of a diagnosed psychotic disorder. (3) To explore the effectiveness of the intervention by analysing primary and secondary outcome data to provide treatment effect estimates, thus informing future trial design.

6.2.3 Study three

Study three presents feasibility findings from the CReSt-R randomised pilot study. The study protocol outlined a number of feasibility indicators, identifying three progression criteria in the areas of recruitment, retention, and acceptability. Recruitment and acceptability progression criteria were met along with randomisation and blinding procedures being deemed feasible. Retention of participants was slightly below the progression criterion established in the study protocol with an attrition rate of 19% at T1 and 37% at T2. This is discussed in study two in the context of the COVID-19 pandemic.

Although not a primary aim of the study design, exploratory statistical analyses were completed with descriptive statistics for both intervention and control groups presented in study three. Linear mixed-effects model (LMM) analysis found evidence that both control and intervention groups showed higher scores on a number of social and occupational functioning, social cognitive and symptom outcome measures over the duration of the study and follow-up time points. However, there was no significant difference observed between the control and intervention group across outcome measures.

Paired sample t-tests were also completed to measure pre-post treatment changes within the intervention group only. A significant improvement from baseline to post-intervention was observed in the primary outcome measure (SOFAS) ($t(12)=-3.31$, $p<0.01$;$d= 0.52$,Table 4); the Bell Lysaker Emotion Recognition Task (BLERT) ($t(12)=-4.61$, $p\leq0.01$;$d=1.31$) and the PANSS total score ($t(12)=2.52$, $p<0.05$;$d=0.70$). These figures are interpreted in the context of the study sample size and their exploratory nature is emphasised. A sample size for future trials was calculated using G*power, on the basis of which it was estimated that a sample size of 94 (i.e., 47 participants in the intervention group, 47 participants in the control group (allocation ratio of 1:1) to have sufficient power (80%, alpha=0.05) to detect changes in SOFAS scores.

6.2.4 Study four

Study four presents acceptability findings from a qualitative study embedded in the CReSt-R trial. A qualitative research design, based on semi-structured interviews and reflexive thematic analysis was employed. Six participants with early psychosis were recruited from the intervention arm of a randomised pilot study, consisting of three women and three men, aged between 22 and 27 years. Four themes concerning the intervention were developed

through the analytical process, which highlighted the importance of (1) a solid therapeutic foundation, (2) multi-directional flow of knowledge, (3) a tailored toolset, and (4) an individual pathway to recovery. Participants also provided pragmatic feedback about how to improve the delivery of the therapy intervention. Both the themes, presented in a pragmatic model, and feedback are described.

In summary, young people with early psychosis described the intervention as acceptable, engaging, helpful, and person-centred, suggesting that if effective, it holds potential value for inclusion as part of future multi-component therapy models of early intervention in psychosis services. Young people in this study also highlighted the importance of an individualised approach to therapy, the vital role of the therapeutic relationship and the ecological validity and value of adopting an assertive outreach delivery, providing therapy outside a conventional clinic setting.

6.3 Contribution of this research (strengths and limitations)

Embarking on this research, there were a number of key gaps in the literature about psychosocial interventions that targeted cognitive and social and occupational function in early psychosis. As mentioned frequently throughout the thesis, much research has focused on the amelioration of clinical symptoms as a primary intervention focus, with other key features of psychosis such as cognition potentially overlooked (Green, 2016). This reflects the broad acknowledgement in our field that a broader array of intervention targets in early psychosis is required to facilitate recovery rather than simply symptom remission (Slade et al., 2011; Hodgekins 2015; Malla & McGorry 2019).

The systematic review and meta-analysis presented in study one provides preliminary evidence of the effectiveness of existing psychosocial interventions and their impact on social and occupational function in the at-risk and early psychosis cohorts. In particular, CRT emerges as a promising intervention outperforming CBTp in terms of impact on validated measures of function (SMD = 0.301, 95% CI, 0.004–0.599). This novel finding, when considered together with a recent comprehensive meta-analysis showing the benefits of CRT in a chronic population (SMD = 0.22 95% CI, 0.16-0.29) (Vita et al.,2021), highlights the importance of targeting cognition even in the early stages of psychosis. In this study, conventional CBTp, focusing on symptom reduction, did not have a significant impact on

function is consistent with a recent Cochrane review of the effectiveness of CBT in schizophrenia (Jones et al., 2018). Another important finding from study one is the impact of multi-component psychosocial interventions on social and occupational functioning and the potential of combining psychosocial therapies in optimising functional outcomes. While the effectiveness of multi-component EIP services has been described (Correll et al., 2018), this study highlights the need for future research to continue to investigate the active ingredients of psychosocial intervention, and the potential of combining therapies to optimise individual, functional recovery.

While this emerging evidence is promising, it should be interpreted in the context of study limitations. Heterogeneity in study design and methodologies is a noted limitation in this area of research. Three trials included in the analysis were not randomised controlled trials. There was also a wide array of functional outcome measures employed across studies ranging from global measures to individualised measures of function. The quality evaluation scale (Rokita et al., 2018) employed for this review, while meeting quality assurance standards, did not account for variation in randomisation and blinding and this should be considered in future reviews and meta-analyses. The level of detail provided in the intervention protocols of each study also varied and so the grouping of interventions into categories was based on descriptions of interventions provided in publications and not necessarily registered trial protocols.

Another aim of this thesis was to explore the feasibility of combining cognitive remediation training and cognitive behavioural therapy in one, multi-component intervention. Given the stage of development of the novel CReSt-R intervention, a feasibility and acceptability study design was implemented, informed by The Medical Research Council's (MRC; Craig et al., 2008; Skivington et al., 2021) framework for evaluating complex interventions. Development and publication of the protocol (study two) contributes to the literature and open science in sharing processes and methodologies for potential future replication. The intervention largely met the progression criteria defined and provides preliminary findings to inform future trials in this area (study three). The study sample size accorded with that deemed acceptable for a pilot study (Browne, 1995; Lancaster et al., 2005). The biggest limitation of study three is that it was completed during the COVID-19 pandemic. Set against a tapestry of emerging public health guidelines, restrictions, and lockdowns, it was not possible for all feasibility indicators to be adequately explored (e.g. cost, therapy fidelity). In the same light, exploration of the evidence that combining CRT and CBT would lead to improved outcomes for

individuals in the early stages of psychosis, should also be interpreted in the context of sample size and delivery of the intervention during the COVID-19 pandemic. Whilst the exploratory statistical analysis is reported, these limitations need to be considered. Informing future sample size based on the pilot primary outcome measure (SOFAS) data is useful for future research.

While study one reports a wide variety in study design and methodologies in the area of psychosocial intervention in early psychosis, there is a dearth of research in the area of acceptability of such interventions. Attrition rates are often used as proxy of acceptability of an intervention (Vita et al., 2022) however this is inadequate in providing meaningful detail and the perspective of the participant. Study four of this thesis, focuses on the acceptability of the novel, CReSt-R intervention. The themes developed in study four provide a unique insight from the perspective of the participant and highlight both strengths of the intervention and potential barriers to engagement. The thematic model presented in study four, while specific to the CReSt-R intervention and therefore not generalisable, may nonetheless be useful in informing future intervention protocol design and certainly in future definitive trial of the CReSt-R intervention. A limitation of study four is that although all intervention participants were invited to complete the semi-structured interviews, none of those who left the trial early opted in for the qualitative interviews. This leaves a gap in knowledge around other potential barriers to engagement in the study process and therapy intervention and is important to address in future acceptability trials.

6.4 Implications for research

This doctoral research provides preliminary evidence of the value of psychosocial interventions targeting functional recovery in early psychosis and the feasibility and acceptability of delivering a combined cognitive remediation training and social recovery therapy. The meta-analysis (study one) identifies study heterogeneity as a major limitation in the current literature and collating high-quality evidence for the impact of psychosocial intervention on social and occupational function in early psychosis. There needs to be emphasis placed on open science practices (e.g., psychosocial trial registration), consistency in reporting intervention protocols to promote replicability and a consensus on outcome measures utilized in future research trials. Open science is however, not without its challenges and the developmental nature of these evolving practices needs to be balanced with current ones (Mirowski, 2018). In a recent umbrella review of (network) meta-analyses of randomised controlled trials (RCTs) comparing psychosocial interventions to treatment as

usual, Solmi et al. (2022) reported a need for more follow-up RCTs of psychosocial interventions and better designed meta-analyses. Specific to early psychosis, they recommend further research of CRT to confirm efficacy in this cohort (Solmi et al., 2022).

However, going straight to an RCT is neither always feasible nor indeed recommended in complex interventions. Complex interventions are recognised to require a different approach, moving away from a linear, cause-effect model to a more iterative, systems-based approach (Greenhalgh & Papoutsi, 2018). The feasibility and acceptability studies in this thesis provide preliminary data for the CReSt-R intervention within the MRC complex intervention framework. Given the added complexity of conducting the study and delivering the intervention during the COVID-19 pandemic, it is recommended that future research of the CReSt-R intervention remains within the feasibility phase of the MRC framework (See Figure 1). A focus of further feasibility studies should include a consideration of context - such as provision of CREST-R in the context of the newly established EIP services in Ireland, engagement with stakeholders (e.g., developing public patient involvement) and refining the intervention.

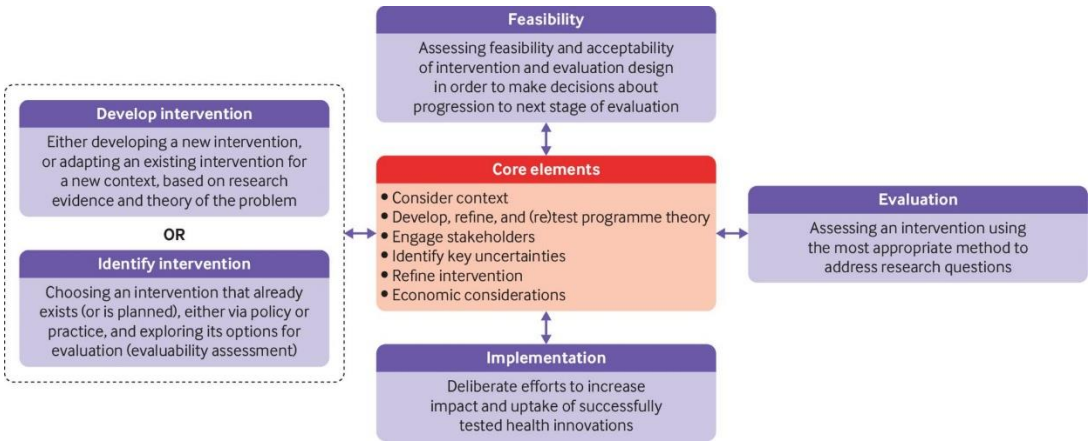


Figure 1. Medical Research Council Framework for evaluating Complex Intervention (Skivington et al., 2021)

A common thread weaved through all four studies of this doctoral thesis has been the emphasis on the importance of focusing on social and occupational function as an outcome in early psychosis. Study one highlighted the heterogeneity of functional outcome measures used in psychosocial intervention trials, ranging from global measures of function to more crude measures such as whether an individual is in employment or education. In the CReSt-R

study design, two social and occupational functioning measures were used, namely the SOFAS and Time Use Survey. While the SOFAS was feasible in terms of assessment and capturing change over designated time points the Time Use Survey proved problematic in validity and reliability, particularly during a time when the time use of the general population was altered in response to the global pandemic. This author recommends further research into how social and occupational function is measured in early psychosis trials. Asbo et al. (2022) call for a consensus definition of clinical recovery in first-episode psychosis. Within their 10-year follow up study in first-episode psychosis, they also highlight the challenge in measuring function and suggest a potential combination of observer-rated and self-report measure (Asbo et al., 2022). Consensus on a definition and measurement of function in early psychosis is identified as a current gap in the literature and a priority for future research.

6.5 Implications for practice

While in recent times there has been advances in bridging the gap between research and practice with an increased focus on implementation science, in reality it still remains a significant challenge (Stirman et al., 2016). As mentioned, this research was informed by the feasibility phase of the MRC complex intervention framework (Skivington et al., 2021), and therefore no direct implications for practice are concluded. Recommendations for future research as discussed above however, may in time inform future clinical guidelines. Current clinical guidelines focus on the provision of pharmacological intervention in conjunction with several specific psychosocial interventions (namely, cognitive behavioural therapy for psychosis (CBTp), family-based interventions and supported employment) (National Institute for Health and Care Excellence (NICE), 2014,2015). Of note, cognitive interventions such as CRT are not included in the current NICE guidelines for early psychosis despite a growing body of evidence for same. Study one adds to the emerging evidence of the effectiveness of CRT on functional outcomes in early psychosis, providing a foundation for future research.

Another common thread which emerged throughout the CReSt-R studies was the concept of community-based, assertive outreach approaches. In study one, a sub-group analysis demonstrated those interventions delivered in a community setting appeared to have a greater impact on function than those delivered in conventional clinical settings. The SRT intervention component, as part of the CReSt-R intervention protocol (study two), employs on assertive outreach approach. This approach was highlighted as contributing to the

acceptability of the intervention to young people in study four. While this observation is in the context of the size and scope of this doctoral research it is nonetheless an important consideration. In 2021, the World Health Organisation highlighted the importance of person-centred, human rights-based and recovery-oriented care, providing guidance on the provision of mental health services in the community (WHO, 2021). This is an important consideration for the future delivery of mental health services in Ireland and internationally.

Engaging stakeholders is a core element of the MRC framework. Including clinicians, patients, family members and international research collaborators in the research process was a core activity of the CReSt-R studies. While not having a direct impact on service provision/practice this public patient involvement activity created dialogue around research practices, and current barriers and facilitators of implementing evidence-based intervention in the context of Irish mental health services, enriching the research process. Further development of public-patient involvement at all stages of engagement from consultation to co-design is a future priority in this area of research.

6.6 Reflections on the collaborative doctoral award programme experience

Embarking on the PhD process has been both a challenging and rewarding experience. I recall seeing a press release from the University of Galway back in 2018 detailing an award of over a million euro from the Irish Health Research Board for youth mental research. At the time, my first thought was 'I wish I had some of that funding.' I had recently taken up post as the Senior Occupational Therapist for the disability support service at the university and on my first day had a waiting list of 63 students waiting for Occupational Therapy support; over 70% of the referrals were for mental-health related difficulties and there were no established intervention protocols at that time. Learning more about YOULEAD, in particular the three pillars of research (epidemiology, barriers to engagement and treatment) and the planned interdisciplinary nature of the work appealed to me and motivated me to apply for the programme. I am beyond glad that I did (even with COVID-19 thrown in the mix).

I have always had an interest in evidence-based treatments, in particular those targeting cognition and functional rehabilitation and recovery. My first exposure to cognitive rehabilitation was a hard copy, paper-and-pencil-based version of Kit Malia's Brain Tree training on my first clinical placement in Scotland in 2008. Years later, my interest in research continued while working in a number of rehabilitation hospitals in the US, tracking

functional outcome data for stroke and brain injury patients, contributing to maintaining Joint Commission certifications.

With almost a decade of clinical experience under my belt, it was nerve wrecking, to say the least, to return to an academic setting. A healthy dose of imposter syndrome ensued; however, I was not alone in this regard. Beginning the PhD process as part of a CDA group was invaluable, another trainee was also returning from clinical practice, and we climbed the steep learning curve together.

Having spent years writing in shorthand and communicating in acronyms and abbreviations in acute hospital settings, becoming a fluid, academic writer was a challenging process for me (and is an ongoing process). In this regard, the mentor/mentee relationship with my supervisor was integral in developing my skills. We adopted an apprenticeship model whereby I submitted work for feedback, at times we wrote collaboratively in real time and as time passed my confidence and writing ability flourished. Similarly, statistics was another area which required additional training. As part of the YOULEAD funding, I was able to attend workshops and seek guidance from a consultant statistician which in turn developed my skills in this area.

For study one, collaborating with the co-authors was my first experience of preparing and submitting a manuscript for publication. The apprenticeship model of writing was in action, receiving feedback on writing in addition to contribution from co-authors on the meta-analysis methodology and manuscript progression. This iterative process along with the process of submission to a journal, receiving an initial rejection and reviewer feedback was an invaluable learning experience for me. Developing the study protocol with my supervisor and renowned collaborators was another iterative process which challenged me in communicating knowledge and research to date in an academic arena. Receiving feedback on the protocol writing demonstrated I was making strides in my writing ability.

I was in my element delivering the CReSt-R intervention, providing almost 300 hours of therapy. Being the primary treating therapist, I relied upon a research assistant to complete outcome measure assessments, while I completed quality control checks and led the overall study process and subsequent data analysis and feasibility study write up. For study four I had the opportunity to collaborate with qualitative researchers and took the lead in study design, analysis, and write-up of the acceptability study.

Additional activities undertaken as part of the CDA programme and personal highlights of the PhD experience were co-founding the YOULEAD Youth Advisory Panel (YAP) with my fellow trainee, Emer Conneely, and completing a national placement with Shine, a national organisation dedicated to campaigning for the rights and empowerment of all people affected by mental ill health. These activities are described in more detail in the appendices.

My skillset in quantitative and qualitative methodologies in addition to academic writing has shown tremendous growth since the first year of the programme. Additional workshops in leadership and communication skills have also contributed to an increased confidence in my abilities. I now describe myself as a clinical academic (less reluctantly than before, although the imposter has not completely vanished). I continue to have areas I would like to improve my skillset in and hope to pursue postdoctoral training in implementation science and statistics in the near future. I am grateful for the vast array of learning opportunities provided by being part of the Youlead programme. I have truly learned a great deal, both personally and professionally, throughout this process and look forward to continuing my research journey.

6.7 Conclusions

To conclude, cognition is an important (and often overlooked) intervention target in early intervention in psychosis. Multi-component interventions appear to have the greatest impact on functional outcomes. New evidence emerging from this thesis highlights the effectiveness of psychosocial intervention on social and occupational function while reporting on methodological limitations and recommendations for optimising future research study design. New feasibility and acceptability data of a novel psychosocial intervention is also reported, providing a platform for further development of the intervention. Consensus studies of the definition of clinical recovery, measures of social and occupational functioning with the inclusion of public patient involvement at the core, is a recommendation for future research.

6.8 References

Åsbø, G., Ueland, T., Haatveit, B., Bjella, T., Flaaten, C. B., Wold, K. F., Widing, L., Engen, M. J., Lyngstad, S. H., Gardsjord, E., Romm, K. L., Melle, I., & Simonsen, C. (2022). The Time is Ripe for a Consensus Definition of Clinical Recovery in First-episode Psychosis: Suggestions Based on a 10-Year Follow-up Study. *Schizophrenia bulletin*, *48*(4), 839–849. https://doi.org/10.1093/schbul/sbac035

Browne R. H. (1995). On the use of a pilot sample for sample size determination. *Statistics in medicine*, *14*(17), 1933–1940. https://doi.org/10.1002/sim.4780141709

Correll, C., Galling, B., Pawar, A., Krivko, A., Bonetto, C., & Ruggeri, M. et al. (2018). Comparison of Early Intervention Services vs Treatment as Usual for Early-Phase Psychosis. *JAMA Psychiatry*, *75*(6), 555. doi: 10.1001/jamapsychiatry.2018.0623

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., Petticrew, M., & Medical Research Council Guidance (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *British Medical Journal (Clinical research ed.)*, *337*, a1655. https://doi.org/10.1136/bmj.a1655

Green, M. (2016). Impact of Cognitive and Social Cognitive Impairment on Functional Outcomes in Patients With Schizophrenia. *The Journal Of Clinical Psychiatry*, 77(Suppl 2), 8-11. doi: 10.4088/jcp.14074su1c.02

Greenhalgh, T., & Papoutsi, C. (2018). Studying complexity in health services research: desperately seeking an overdue paradigm shift. *BMC medicine*, *16*(1), 95. https://doi.org/10.1186/s12916-018-1089-4

Hodgekins, J., French, P., Birchwood, M., Mugford, M., Christopher, R., Marshall, M., Everard, L., Lester, H., Jones, P., Amos, T., Singh, S., Sharma, V., Morrison, A. P., & Fowler, D. (2015). Comparing time use in individuals at different stages of psychosis and a non-clinical comparison group. *Schizophrenia research*, *161*(2-3), 188–193. https://doi.org/10.1016/j.schres.2014.12.011

Jones, C., Hacker, D., Meaden, A., Cormac, I., Irving, C. B., Xia, J., Zhao, S., Shi, C., & Chen, J. (2018). Cognitive behavioural therapy plus standard care versus standard care plus other psychosocial treatments for people with schizophrenia. *The Cochrane database of systematic reviews*, *11*(11), CD008712. https://doi.org/10.1002/14651858.CD008712.pub3

Lancaster, G. A., Dodd, S., & Williamson, P. R. (2004). Design and analysis of pilot studies: Recommendations for good practice. *Journal of Evaluation in Clinical Practice*, *10*(2), 307–312. https://doi.org/10.1111/j..2002.384.doc.x

Malla, A., & McGorry, P. (2019). Early Intervention in Psychosis in Young People: A Population and Public Health Perspective. *American journal of public health*, *109*(S3), S181–S184. https://doi.org/10.2105/AJPH.2019.305018

Mirowski, P. (2018). The future(s) of open science. *Social Studies of Science*, *48*(2), 171–203. https://doi.org/10.1177/0306312718772086

National institute for Health and Care Excellence (NICE) (2014) Psychosis and Schizophrenia in Adults: Prevention and Management, National Clinical Practice Guidelines (CG178). Retrieved from https://www.nice. org.uk/guidance/cg178/evidence/full-guideline-490503565.

National institute for Health and Care Excellence (NICE) (2015) Quality Standards for Mental Health Early Intervention Service Provision for Adults with Psychosis or Schizophrenia. Retrieved from https://www.nice. org.uk/guidance/qs80.

Rokita, K. I., Dauvermann, M. R., & Donohoe, G. (2018). Early life experiences and social cognition in major psychiatric disorders: A systematic review. *European Psychiatry*, 53, 123–133. http://doi.org/10.1016/j.eurpsy.2018.06.006

Skivington, K., Matthews, L., Simpson, S. A., Craig, P., Baird, J., Blazeby, J. M., Boyd, K. A., Craig, N., French, D. P., McIntosh, E., Petticrew, M., Rycroft-Malone, J., White, M., & Moore, L. (2021). A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *British Medical Journal (Clinical research ed.), 374*, n2061. https://doi.org/10.1136/bmj.n2061

Slade M, Bird V, Le Boutillier C, Williams J, McCrone P, Leamy M (2011). REFOCUS Trial: protocol for a cluster randomised controlled trial of a pro-recovery intervention within community based mental health teams. *BMC Psychiatry*, 11:185

Solmi, M., Croatto, G., Piva, G., Rosson, S., Fusar-Poli, P., Rubio, J. M., Carvalho, A. F., Vieta, E., Arango, C., DeTore, N. R., Eberlin, E. S., Mueser, K. T., & Correll, C. U. (2022). Efficacy and acceptability of psychosocial interventions in schizophrenia: systematic overview and quality appraisal of the meta-analytic evidence. *Molecular psychiatry*, 10.1038/s41380-022-01727-z. Advance online publication. https://doi.org/10.1038/s41380-022-01727-z

Stirman, S. W., Gutner, C. A., Langdon, K., & Graham, J. R. (2016). Bridging the Gap Between Research and Practice in Mental Health Service Settings: An Overview of Developments in Implementation Theory and Research. *Behavior therapy*, *47*(6), 920–936. https://doi.org/10.1016/j.beth.2015.12.001

Vita, A., Barlati, S., Ceraso, A., Nibbio, G., Ariu, C., Deste, G., & Wykes, T. (2021). Effectiveness, Core Elements, and Moderators of Response of Cognitive Remediation for Schizophrenia: A Systematic Review and Meta-analysis of Randomized Clinical Trials. *JAMA psychiatry*, *78*(8), 848–858. https://doi.org/10.1001/jamapsychiatry.2021.0620

Vita, A., Barlati, S., Ceraso, A., Deste, G., Nibbio, G., & Wykes, T. (2022). Acceptability of cognitive remediation for schizophrenia: a systematic review and meta-analysis of randomized controlled trials. *Psychological medicine*, 1–11. Advance online publication. https://doi.org/10.1017/S0033291722000319

World Health Organisation (WHO) (2021). Guidance on community mental health services: promoting person-centred and rights-based approaches. Geneva (Guidance and technical packages on community mental health services: promoting person-centred and rights-based approaches). Licence: CC BY-NC-SA 3.0 IGO

Appendix A: Prisma Checklist for Study 1

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	1
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	5
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7

Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	8
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	7
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	18

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	19
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	20
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	9
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	9
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	8
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	37
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	18
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	8
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	20
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	22

Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	22
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	24
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	8,24

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: **www.prisma-statement.org**.

Appendix B: Published version of study 1

Psychological Medicine

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Original Article

Cite this article: Frawley E, Cowman M, Lepage M, Donohoe G (2021). Social and occupational recovery in early psychosis: a systematic review and meta-analysis of psychosocial interventions. *Psychological Medicine* 1–12. https://doi.org/10.1017/S003329172100341X

Received: 14 March 2021
Revised: 20 July 2021
Accepted: 29 July 2021

Key words:
Early psychosis; occupational function; psychosocial intervention; recovery; social function

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CAMBRIDGE UNIVERSITY PRESS

Social and occupational recovery in early psychosis: a systematic review and meta-analysis of psychosocial interventions

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Abstract

Background. Psychosis, even in its early stages, ranks highly among the causes of disability worldwide, resulting in an increased focus on improved recovery of social and occupational functioning. This study aimed to provide an estimate of the effectiveness of psychosocial interventions for improving functioning in early psychosis. We also sought evidence of superiority between intervention approaches.

Methods. An electronic search was conducted using PubMed and PsycINFO to identify original articles reporting on trials of psychosocial interventions in early-stage psychosis, published up to December 2020 and is reported following PRISMA guidelines. Data were extracted on validated measures of functioning from included studies and pooled standardised mean difference (SMD) was estimated.

Results. In total, 31 studies involving 2811 participants were included, focusing on: cognitive behavioural therapy for psychosis (CBTp), family-based therapy, supported employment, cognitive remediation training (CRT) and multi-component psychosocial interventions. Across interventions, improved function was observed (SMD = 0.239; 95% confidence interval 0.115–0.364, $p < 0.001$). Effect sizes varied by intervention type, stage of illness, length and duration of treatment and outcome measure used. In particular, interventions based on CRT significantly outperformed symptom-focused CBT interventions, while multi-component interventions were associated with largest gains.

Conclusions. Psychosocial interventions, particularly when provided as part of a multi-component intervention model and delivered in community-based settings are associated with significant improvements in social and occupational function. This review underscores the value of sensitively tracking and targeting psychosocial function as part of the standard provided by early intervention services.

Introduction

Psychosis, even in its early stages, is associated with significant disability, causing it to be ranked ahead of paraplegia and blindness in those aged 18–35 in terms of years lived with disability. Current pharmacological treatments target positive symptoms (hallucinations and delusions) of psychosis, but not other features of illness, including negative and affective symptoms and cognitive deficits, which more accurately predict functional outcome than positive symptoms alone (Green, 2016). Consequently, even after successful treatment of positive symptoms, little benefit to functional outcome may result, suggesting a need to expand the range of treatment targets (Hodgekins et al., 2015; Malla & Mcgorry, 2019).

Despite this, psychosocial interventions for psychosis have often focused only on clinical/symptom improvement as the main outcome, leading to a conclusion of equivalence between psychosocial treatments in terms of modest treatment benefits (Fusar-Poli et al., 2015). However, focusing on only one illness dimension (e.g. positive symptom severity), ignores the range of factors contributing to overall loss of social/occupational function, measured in terms of reduced social engagement and significant underemployment (~20% of individuals with psychosis go on to independent employment). In first-episode psychosis, a meta-analysis by Santesteban-Echarri et al. (2017) found that duration of untreated psychosis, cognitive function and remission of positive and negative symptoms were each *independently* related to functional recovery (Santesteban-Echarri et al., 2017). Similarly, Stouten, Veling, Laan, Van Der Helm, and Van Der Gaag (2017) found that poorer functioning was associated with higher levels of negative symptoms, poorer cognitive function and poorer social cognition (explaining 39.4% of variance) (Stouten et al., 2017). We observed similar results in first-episode psychosis, and also identified premorbid adjustment as another relevant factor (Jordan et al., 2014, 2018). By contrast, affective or positive symptoms did not have a marked impact on psychosocial functioning.

Here, we present a systematic review and meta-analysis of psychosocial interventions delivered during the early phase of psychosis, i.e. either during the high-risk stage, or within the 5 years after first diagnosis based on a range of outcomes relevant to social and occupational disability and recovery. We sought to include studies which *evaluated changes in level of social and occupational function* in early psychosis, either directly by targeting some aspect of function, or indirectly by targeting clinical or contextual factors negatively impacting on function. These factors included: (1) clinical symptom severity, (2) hospital readmission rates, (3) levels of distress, (4) quality of life, (5) level of cognitive function and (6) level of social and occupational function. In addition to reviewing evidence for the efficacy and/or effectiveness of these interventions, we also sought evidence of superiority between these approaches while taking into consideration whether social and occupational functioning was considered a primary or secondary outcome in included studies.

Method

Study selection

An electronic search was conducted using PubMed and PsycINFO to identify original articles reporting on trials of psychosocial interventions in early-stage psychosis, published up to December 2020. Early-stage psychosis was defined as including the high-risk stage, and anytime within 5 years of a first diagnosis of psychotic disorder. Psychosocial interventions were defined as psychologically and socially orientated interventions which targeted and then evaluated changes in the level of social and occupational function (either as a primary or secondary outcome). Social and occupational functioning was assessed using one or more of the following: (1) global functioning as measured by standardised measures [e.g. global assessment of function (GAF), Social and Occupational Functioning Assessment Scale (SOFAS), Social Functioning Scale (SFS)], Personal Social Performance scale (PSP); and (2) individual definitions of functioning covering one or more of the following areas: vocational functioning, educational functioning, degree of independence and social functioning (i.e. relationships).

Search strategy

An electronic search was conducted using PubMed and PsycINFO to identify articles investigating the effects of psychosocial interventions on psychosocial function in first-episode psychosis using the following search terms: ('Early psychosis' OR 'clinical high risk' AND 'Psychosis' OR 'ultra-high risk' AND 'Psychosis') OR ('first episode psychosis' OR 'first episode schizophrenia' OR 'recent onset psychosis' OR 'recent onset schizophrenia' OR 'early psychosis' OR 'early schizophrenia') AND ('social function*' OR 'social outcome*' OR 'global function*' OR 'global outcome*' OR 'community function*' OR 'community outcome*' OR 'occupational function*' OR 'occupational outcome*' OR 'work function*' OR 'work outcome*' OR 'vocational function*' OR 'vocational outcome*' OR 'recovery' OR 'quality of life' OR 'employment' OR 'global assessment of function' OR 'social and occupational functioning assessment scale' OR 'functioning scale' OR 'disability') AND ('psychosocial' OR 'psychological' OR 'Intervention' OR 'therapy' OR 'CBT' or 'Cognitive behav*'OR 'CRT' or 'Cognitive remed*' OR ' Social' or 'Social skills' OR 'IPS' OR 'Individual placement support' OR 'Vocation*' OR 'Online' OR 'Moderated' or 'Moderated support' OR 'Family Therapy' OR 'Assertive outreach' OR 'Outreach' 'trial' OR 'program' OR 'randomised control trial' OR 'RCT' OR 'pilot' OR 'study').Searches were limited to original, full text articles written in English and published in peer-reviewed journals up to December 2020. The initial electronic search was conducted by two authors (EF and MC). It was fully replicated in a second, independent search. No discrepancies were noted with both search results cross-checked by a third author (GD).

Quality assurance

The quality assessment of included studies was based on the revised version of the quality evaluation scale employed in our previous reviews as follows: (1) the clinical sample was representative of the target population (eligible cases were recruited in hospitals and/or mental health services settings with a diagnosis based on well-established clinical diagnostic manuals), (2) the clinical sample was appropriately matched to the control group (patients and controls matched for at least two confounding variables: age and/or sex and/or education level, (3) the authors performed sample size calculations and/or power analysis, (4) the study used well-established measures of psychosocial functioning either as a primary or secondary outcome measure, (5) the study provided adequate detail on the psychosocial intervention provided and (6) the authors reported effect sizes and/or confidence intervals (CIs) of their main findings. Each item scored one point if the criterion was met and the overall quality score was a sum of the met criteria (Rokita, Dauvermann, & Donohoe, 2018).

Data extraction

Data were extracted on validated measures of functioning from included studies. Relevant data extracted also included study and participant characteristics (nature of the intervention, intervention length, follow-up length, control condition, number of sessions, age, percent male, diagnoses, medication use, and illness duration). The authors extracted data independently and discrepancies were resolved by consensus (EF, MC and GD).

Data analysis

Pooled standardised mean difference (SMD – Cohen's *d*) was estimated with Comprehensive Meta-Analysis Software (CMA), Version 3 (Borenstein, Hedges, Higgins, & Rothstein, 2013). SMD was chosen as the effect size as raw mean and standard deviation scores were provided for most included studies and to allow for the heterogeneity in functional measures used across studies. Due to the variability across studies in length of follow-up assessment, immediately post-intervention data were included in the analyses. For continuous variables, where possible, raw data (pre and post means and standard deviations) was used to estimate effect sizes. Where raw data were unavailable, sample size and *F* statistics were used. Two studies provided dichotomous variables for which events and sample size were used (i.e. employed *v.* unemployed). CMA allows for the inclusion of different data formats in the same analysis (Borenstein, Hedges, Higgins, & Rothstein, 2011). Effect sizes were pooled using random-effects models. Separate analyses were conducted for five different intervention groups, and an overall summary analysis was conducted including all psychosocial intervention studies. For two intervention groups (supported employment and

family-based interventions) only three studies were included in the meta-analysis, due to the small number of studies in each group these analyses should be considered exploratory. Subgroup analyses were performed to account for differences in effect size based on participant, intervention and measurement characteristics.

Heterogeneity and publication bias

Heterogeneity was explored using the Q statistic and the I^2 statistics. The Q statistic measures the dispersion of all effect sizes about the mean effect size, the I^2 statistic measures the ratio of true variance to total variance (Borenstein et al., 2011). Publication bias was examined by visual inspection of funnel plots, the trim-and-fill method (Duval & Tweedie, 2000) and the regression test (Egger, Smith, Schneider, & Minder, 1997).

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Study characteristics

The literature search identified 1233 relevant publications of which 20 were found to meet inclusion criteria. A further 11 studies were identified through additional sources. In total, 31 studies involving 2811 participants were included in our analysis (see Fig. 1 for PRISMA flow diagram and Table 1 for study characteristics). Studies are categorised by psychosocial intervention type as follows: cognitive behavioural therapy (CBT), family-based therapy (FBT), supported employment, cognitive remediation training (CRT) and multi-component psychosocial interventions.

Meta-analysed results for all intervention categories for which relevant data could be ascertained are presented in Fig. 2 in terms of both the total effect and the effects of individual interventions where these could be estimated (n studies = 31). In summary these studies included 11 based on ultra-high-risk participants (n = 1040), two studies based on prodromal patients (n = 126), 11 first episode psychosis (FEP) studies (n = 1171), and a further seven studies of early psychosis (less than or equal to 5 years since diagnosis) (n = 474). Participants mean age ranged from 15.5 to 29.3 years (mean = 22.3, S.D. = 3.6). Mean percentage of male participants across studies was 63.3%. Across these, 22 studies included measures of global function (GAF, SOFAS, TUS, SAS, SFS, RFS, PSP and LSP-39) four studies included measures of social functioning (GFS, SBS, social behaviour and social attainment), three studies included measures of employment, and two studies included a measure of functional capacity (UPSA-B). For a description of validated functioning measures see online Supplementary Table S1. Intervention length ranged from 2 months to 3 years (mean = 8.7, S.D. = 7.7). Number of sessions ranged from 9 to 128 (mean = 32.1, S.D. = 24.2).

Across the total number of studies included, an effects size SMD = 0.239 [95% CI (0.115–0.364), $p < 0.001$] was observed, suggesting a benefit of psychosocial interventions generally in terms of social and occupational outcomes (see Fig. 2). When non-ramdomised controlled trial (RCT) studies (Granö et al., 2016; Macneil et al., 2012; Mcfarlane et al., 2015) were excluded from the analysis the effect size SMD changed to 0.251 (Granö et al., 2016; Macneil et al., 2012; Mcfarlane et al., 2015) (see online Supplementary Fig. S11).

Significant heterogeneity was noted for all intervention modalities, except for CBT (see online Supplementary Table S2). This is likely reflecting variability across studies in sample size, intervention length, number of sessions, participant diagnosis and outcome measures. For CBT, CRT and multi-component psychosocial interventions, no evidence of significant publication bias was found. Similarly, when all studies are considered together, no evidence of significant publication bias was observed. The limited number of studies in the supported employment and family-based intervention groups prevented publication bias from being thoroughly tested (see online Supplementary Figs. S1–S4).

CBT in at risk and early psychosis

CBT for psychosis (CBTp) was developed with the primary aim of reducing clinical symptom severity and relapse rates, rather than to improve social and occupational function. Where social and occupational outcomes are reported, this is often as a secondary aim, if at all. CBTp is recommended by the National Institute for Health and Care Excellence for people living with a diagnosis of schizophrenia [National Institute for Health and Care Excellence (NICE), 2014]. A recent Cochrane review of CBTp concluded, however, that there remains a lack of robust evidence to support its clinical use in addition to standard care, on account of low-quality data available (Jones et al., 2018). Similarly, Bighelli et al. (2018) reported that while CBTp was associated with decreased positive symptoms, confidence in the estimates ranged from moderate to very low (Bighelli et al., 2018). Equally Laws, Darlington, Kondel, Mckenna, and Jauhar (2018) in their meta-analysis reported that CBTp has a small therapeutic effect on functioning at end-of-trial, but that this benefit did not persist at follow-up (Laws et al., 2018).

Based on our review of studies carried out in early psychosis, only six studies were identified that investigated the effects of CBTp – as a single-component intervention – on social and occupational functioning. Of these, five studies focused on clinical high-risk groups, none of which found evidence that CBTp was associated with improvements on the measures of social and occupational function, which was variously measured using the GAF, SAS, SFS, Time Use and the SOFAS (Addington et al., 2011; Bechdolf et al., 2007; Ising et al., 2016; Morrison et al., 2004; Stain et al., 2016).

One study of CBTp targeted psychosocial function in first episode psychosis (Jackson et al., 2007). It compared CBTp to a befriending intervention and demonstrated no significant difference between intervention groups post treatment (Jackson et al., 2007). Several additional studies included CBTp as one component of a multi-component intervention; these are reviewed below in the section on multi-component psychosocial interventions.

One question raised by these findings is whether a failure to see improvements in social and occupational function derives from a failure to ameliorate clinical symptoms, or whether successful improvement of clinical symptoms simply was not associated with any effects on functional outcomes. This question reflects a broader critique of CBTp in which the ability of CBT

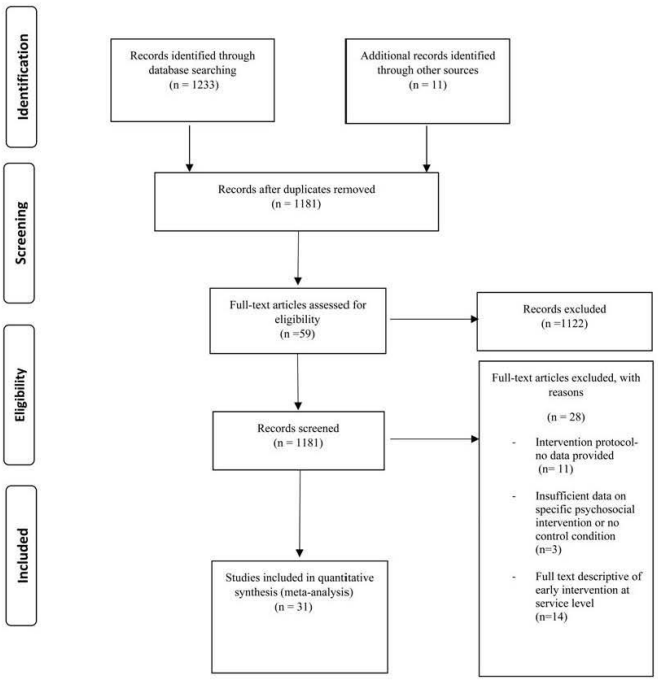


Fig. 1. PRISMA flow diagram of studies selected for systematic review and meta-analysis.

to lead to improvements in clinical state has been questioned (Fusar-Poli et al., 2015; Jones et al., 2018; Laws et al., 2018; Velthorst et al., 2015). Of the four studies above, however, each reported evidence that CBTp led to lowered symptoms, particularly positive symptoms, in the absence of a knock-on benefit to social and occupational function (Addington et al., 2011; Ising et al., 2016; Morrison et al., 2004). This was not always superior to the control condition (Stain et al., 2016). Ising et al. (2016) further stating social functioning remained impaired even in those remitted from ultra-high-risk status (Ising et al., 2016).

Other approaches to CBT for psychosis have emerged over time, shifting focus from symptoms to specifically targeting social recovery. In such approaches, the emphasis is on addressing barriers to social engagement (e.g. avoidance), and participation in normative life roles. Although there is much overlap with traditional CBTp in terms of collaborative formulation and goal setting, a stronger emphasis is placed on behavioural experimentation outside the clinic and in the person's own social environment to overcome identified barriers. Described as social recovery therapy (SRT), this approach has been demonstrated to lead to significant improvement in function as measured by time spent in structured activity. Importantly, this approach also showed evidence of improvements being maintained over time when compared to a control group receiving treatment a usual (Fowler et al., 2009, 2018; Fowler, Hodgekins, & French, 2019). The degree to which these changes were independent of changes in symptom severity is unclear; missing data on symptoms severity at follow-up assessment time points has meant that this question remains to be answered.

A meta-analysis of the effects of CBT interventions on validated measures of function was non-significant based on a total of eight available studies [SMD = 0.139, 95% CI (−0.021 to 0.299), $p = 0.089$] (see Fig. 2). Five of these eight studies were based on ultra-high risk (UHR) samples. Of note, when the analysis was conducted excluding those UHR studies a difference in effect size and significance was observed (SMD = 0.345, $p < 0.005$) (see online Supplementary Fig. S12). Although only three studies were included in this additional analysis, it is an important exploratory consideration.

Also noteworthy in the CBT intervention group was that the largest of these studies – based on SRT rather than a symptom orientated CBT, was the sole individual study associated with significant gains in psychosocial function (Fowler et al., 2018).

Table 1. Characteristics of studies included in the review and meta-analysis

Study	Participants *N*		Mean age (s.d.)	Intervention	Outcome measures	Main findings
	Intervention group	Control group				
Cognitive behavioural therapy						
Addington et al. (2011)	19	16	20.8 (4.5)	CBTp	GAF SAS SIAS SFS	No sig. impact in function
Bechdolf et al. (2007)	29	38	25.2 (5.3)	CBTp	SAS	Sig. improvement in SAS however no sig. diff. between CBTp and control condition
Fowler et al. (2009)	33	38	27.8 (6.1)	SRT	Time use	No sig. impact on function in affective psychosis group Sig. improvement in function in non-affective psychosis group 25% of individuals with non-affective psychosis engaged in paid work in the year following end of SRT
Fowler et al. (2018)	72	71	24.8 (8.3)	SRT	Time use	SRCBT→increase of 8.1 h in structured activity
Ising et al. (2016)	80 (UHR)	90	22.7 (5.6)	CBTp	SOFAS	No sig. impact in function
Jackson et al. (2007)	31	31	22.5 (3.9)	CBTp	SOFAS	No sig. impact in function
Morrison et al. (2004)	97 (UHR)	98	22.0 (4.5)	CBTp	GAF	No sig. impact in function
Stain et al. (2016)	17 (UHR)	17	16.5 (3.2)	CBTp	GAF SOFAS	No sig. impact in function
Family-based intervention						
Granö et al. (2016)	28 (UHR)	28	15.5 (1.6)	Family based intervention	GAF	Improvement in functioning
Mcfarlane et al. (2015)	147 (CHR)	57	16.4 (3.3)	Family based intervention	GAF GFR GFS	Improvement on GAF, work, and school participation
Miklowitz et al. (2014)	55 (CHR)	47	17.4 (4.1)	Family based intervention	GAF	>19 years: >improvement in GAF if received family intervention 16–19 years: >improvement in GAF if received control condition
Supported employment						
Killackey et al. (2008)	20	21	21.3 (2.4)	IPS	Employment SOFAS	IPS>sig. higher employment and reduced welfare benefits
Killackey et al. (2019)	66	60	20.4 (2.4)	IPS	Employment SOFAS	IPS>sig. higher employment (71%)
Rosenheck et al. (2017)	144	83	23.2 (5.2)	SEE-supported employment and education	Participation in work or school	EI associated with > increase in participation in work or school and difference appeared to be mediated by SEE

(*Continued*)

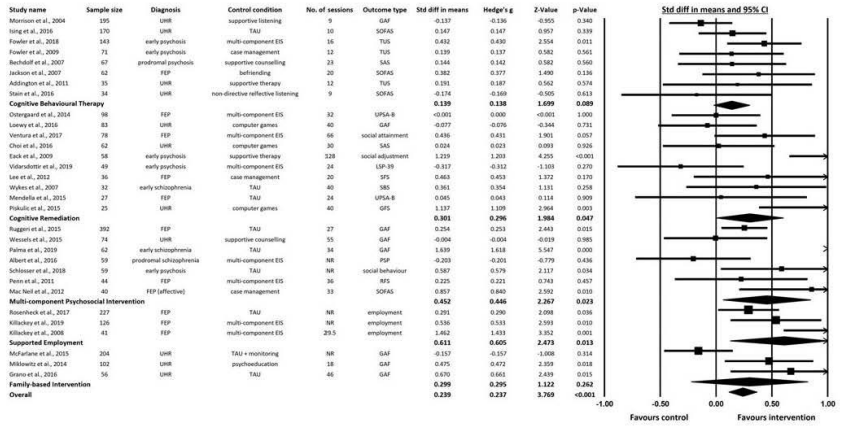
Table 1. (*Continued.*)

Study	Participants *N*		Mean age (s.d.)	Intervention	Outcome measures	Main findings
	Intervention group	Control group				
Cognitive remediation						
Choi et al. (2016)	30 (UHR)	32	18.3 (3.7)	CRT-process speed training	SAS	Improvement in function
Eack et al. (2009/2010)	31	27	25.9 (6.3)	CRT-neurocognition + social skills group	SAS Major Role Inventory GAS	Improvement in social functioning/maintained at 1 year follow-up
Lee et al. (2013)	18	18	22.8 (4.3)	CRT-neurocognition programme + psychoeducation	SFS	CR→improvement in function
Loewy et al. (2016)	50	33	17.8 (3.1)	CRT-auditory processing programme	GAF GFS GFR	Improvement in function
Østergaard Christensen et al. (2014)	51	47	25.0 (3.3)	CRT-neurocognition programme	UPSA-B	No. sig. impact on function
Piskulic et al. (2015)	18 (CHR)	14	19.7 (5.7)	CRT – auditory training	GFS GFR	Sig. improvement in social function
Ventura et al. (2017)	38	40	21.5 (3.0)	CRT-neurocognition programme + group	SAS	Sig. improvement in social functioning
Vidarsdottir et al. (2019)	25	24	24.2 (3.2)	CRT-neurocognition programme + SCIT group	LSP-39 OSA Brief A	No sig. impact on function
Wykes et al. (2007)	21	19	18.2 (2.5)	CRT – Neurocognition + TAU	SBS	Sig. impact on function
Mendella et al. (2015)	16	11	25.0 (3.9)	CCT-Compensatory cognitive training	UPSA-B	No sig. impact on function
Multi-component psychosocial intervention						
Albert et al. (2016)	30 (CHR)	29	26.6 (4.4)	Family treatment, social skills training, assertive treatment approach	SPS	No sig. impact on function
Macneil et al. (2012)	20	20	21.8 (2.1)	CBTp, family therapy, psychoeducation	GAF SOFAS	Sig. improvement in functioning
Palma et al. (2019)	35	27	25.5 (4.8)	CBTp, psychoeducation, cognitive-motivational therapy	GAF	Sig. improvement in functioning
Penn et al. (2011)	22	22	23.5 (3.9)	CBTp, psychoeducation, motivational interviewing, social skills	RFS SSPA	No sig. impact on function
Ruggeri et al. (2015)	239	153	29.3 (9.8)	CBTp, family, intervention, case management	GAF	Sig. improvement in functioning
Schlosser et al. (2018)	38	21	24.3 (2.6)	Mobile application-community peer support, CBTp, goal setting	MAP-SR RFS	Trend towards sig. diff. on MAP-SR No sig. diff. on RFS
Wessels et al. (2015)	31 (CHR)	43	25.2 (5.4)	CBTp, psychoeducation,	GAF	Sig. improvement in function.

Brief-A, Behaviour Rating Inventory of Executive Function; GAF, Global Assessment of Functioning Scale; GAS, Global Assessment Scale; GFR, Global Functioning: Role Scale; GFS, Global Functioning: Social Scale; LSP-39, Life Skills Profile; OSA, Occupational Self-Assessment; MAP-SR, Motivation and Pleasure-Self Report scale; RFS, Role Functioning Scale; SAS, Social Adjustment Scale; SBS, Social Behaviour Schedule; SFS, Social Functioning Scale; SIAS, Social Interaction Anxiety Scale; SOFAS, Social & Occupational Functioning Scale; SSPA, Social Skills Performance Assessment; UPSA-B, UCSD Performance-Based Skills Assessment.

Family-based interventions

Family interventions are recommended by the National Institute for Health and Care Excellence (NICE) clinical guidelines in the treatment of early psychosis [National Institute for Health and Care Excellence (NICE), 2015]. Those at-risk for or in the early stages of psychosis often continue to live with and be supported by family members in the community. It is



Study name	Sample size	Diagnosis	Control condition	No. of sessions	Outcome type	Std diff in means	Hedge's g	Z-Value	p-Value
Morrison et al., 2004	195	UHR	supportive listening	9	GAF	-0.137	-0.136	-0.955	0.340
Ising et al., 2016	170	UHR	TAU	10	SOFAS	0.147	0.147	0.957	0.339
Fowler et al., 2018	143	early psychosis	multi-component EIS	16	TUS	0.432	0.430	2.554	0.011
Fowler et al., 2009	71	early psychosis	case management	12	TUS	0.139	0.137	0.582	0.561
Bechdolf et al., 2007	67	prodromal psychosis	supportive counselling	23	SAS	0.144	0.142	0.582	0.560
Jackson et al., 2007	62	FEP	befriending	20	SOFAS	0.382	0.377	1.490	0.136
Addington et al., 2011	35	UHR	supportive therapy	12	TUS	0.191	0.187	0.562	0.574
Stain et al., 2016	34	UHR	non-directive reflective listening	9	SOFAS	-0.174	-0.169	-0.505	0.613
Cognitive Behavioural Therapy						**0.139**	**0.138**	**1.699**	**0.089**
Ostergaard et al., 2014	98	FEP	multi-component EIS	32	UPSA-B	<0.001	0.000	<0.001	1.000
Loewy et al., 2016	83	UHR	computer games	40	GAF	-0.077	-0.076	-0.344	0.731
Ventura et al., 2017	78	FEP	multi-component EIS	66	social attainment	0.436	0.431	1.901	0.057
Choi et al., 2016	62	UHR	computer games	30	SAS	0.024	0.023	0.093	0.926
Eack et al., 2009	58	early psychosis	supportive therapy	128	social adjustment	1.219	1.203	4.255	<0.001
Vidarsdottir et al., 2019	49	early psychosis	multi-component EIS	24	LSP-39	-0.317	-0.312	-1.103	0.270
Lee et al., 2012	36	FEP	case management	20	SFS	0.463	0.453	1.372	0.170
Wykes et al., 2007	32	early schizophrenia	TAU	40	SBS	0.361	0.354	1.131	0.258
Mendella et al., 2015	27	FEP	TAU	24	UPSA-B	0.045	0.043	0.114	0.909
Piskulic et al., 2015	25	UHR	computer games	40	GFS	1.137	1.109	2.964	0.003
Cognitive Remediation						**0.301**	**0.296**	**1.984**	**0.047**
Ruggero et al., 2015	392	FEP	TAU	27	GAF	0.254	0.253	2.443	0.015
Wessels et al., 2015	74	UHR	supportive counselling	55	GAF	-0.004	-0.004	-0.019	0.985
Palma et al., 2019	62	early schizophrenia	TAU	34	GAF	1.639	1.618	5.547	0.000
Albert et al., 2016	59	prodromal schizophrenia	multi-component EIS	NR	PSP	-0.203	-0.201	-0.779	0.436
Schlosser et al., 2018	59	early psychosis	TAU	NR	social behaviour	0.587	0.579	2.117	0.034
Pein et al., 2011	44	FEP	multi-component EIS	36	RFS	0.225	0.221	0.743	0.457
Mac Neil et al., 2012	40	FEP (affective)	case management	33	SOFAS	0.857	0.840	2.592	0.010
Multi-component Psychosocial Intervention						**0.452**	**0.446**	**2.267**	**0.023**
Rosenheck et al., 2017	227	FEP	TAU	NR	employment	0.291	0.290	2.098	0.036
Killackey et al., 2019	126	FEP	multi-component EIS	NR	employment	0.536	0.533	2.593	0.010
Killackey et al., 2008	41	FEP	multi-component EIS	29.5	employment	1.462	1.433	3.352	0.001
Supported Employment						**0.611**	**0.605**	**2.473**	**0.013**
McFarlane et al., 2015	204	UHR	TAU + monitoring	NR	GAF	-0.157	-0.157	-1.008	0.314
Miklowitz et al., 2014	102	UHR	psychoeducation	18	GAF	0.475	0.472	2.359	0.018
Grano et al., 2016	56	UHR	TAU	46	GAF	0.670	0.661	2.439	0.015
Family-based Intervention						**0.299**	**0.295**	**1.122**	**0.262**
Overall						**0.239**	**0.237**	**3.769**	**<0.001**

Fig. 2. Forest plot of summary statistics (SMD – Cohen's *d*) for intervention groups and overall summary statistics for psychosocial interventions.

widely acknowledged that this experience impacts not only on the individual, but also on family members in terms of their daily functioning, relationships, mental health and community interaction.

Family intervention has typically focused on relapse prevention, often by seeking to enhance communication and problem solving within the family to reduce expressed emotion, stress and the consequent risk of relapse. Only three studies were identified that reported the effects of family therapy on social and occupational function when delivered as a sole intervention (by comparison with multi-component studies reviewed below). Each of these studies focused on clinical high-risk groups. Although the content of family intervention delivered in each study varied, key common elements of each included psychoeducation, communication skills and problem solving for everyday living. Similar to SRT, delivering family therapy as part of, or embedded in, community activities (directly in natural setting of the participant e.g. meeting in a café) featured in two of the studies and described as 'assertive community treatment', or 'community-orientated integrative treatment' (Granö et al., 2016; Mcfarlane et al., 2015). All three studies report a significant improvement in function based on based on both measures of social function and levels of participation in normative life activities such as school or work (Granö et al., 2016; Mcfarlane et al., 2015; Miklowitz et al., 2014). One study further compared the impact of family therapy on psychosocial functioning between those over and under the age of 19, with a stronger treatment effect reported in those over the age of 19 (Miklowitz et al., 2014).

In terms of whether and how these effects related to changes in clinical presentation, two of the three studies reviewed report a significant reduction in symptoms, particularly positive symptoms concurrent to psychosocial improvements (Mcfarlane et al., 2015; Miklowitz et al., 2014). The third study reviewed reported improvement in psychosocial functioning, self-reported depression symptoms and hopelessness in the absence of changes in either self-reported anxiety, or psychosis risk symptoms as measured by the Structured Interview for Psychosis-Risk Syndromes (SIPS) (Granö et al., 2016).

An insufficient number of family therapy studies ($n = 3$) were available to calculate an effects size specifically for family interventions. When reviewed in the overall list of psychosocial studies (online Supplementary Fig. S3), effect sizes differed between studies, with Granö et al. (2016) and Miklowitz et al. (2014) showing significant psychosocial benefits, while the study by Mcfarlane et al. (2015) reported non-significant benefits (Granö et al., 2016; Mcfarlane et al., 2015; Miklowitz et al., 2014). Of note also in the FBT group is that although all three studies included a control condition, both Granö et al. (2016) and Mcfarlane et al. (2015) are not randomised control trials and this also needs to be considered in the interpretation of the exploratory results.

Supported employment

Individuals with lived experience of psychosis often report they place goals of completing their education and gaining employment above addressing their mental health symptoms (Ramsay et al., 2011). Despite these stated goals, the trajectory of young people living with psychosis to complete their education and transition into employment remains low (Rinaldi et al., 2010; Waghorn et al., 2012). Under the umbrella of the supported employment model, the individual placement and support (IPS) model has been integrated into clinical guidelines and several early intervention services and represents a research focus of studies of psychosocial function in early psychosis [National Institute for Health and Care Excellence (NICE), 2015]. IPS is designed to assist people with severe mental illness to return to mainstream employment, the overarching philosophy being that anyone is capable of partaking in paid, competitive employment with careful consideration of job type, job environment and with an effective support system in place.

IPS is based on eight key principles; zero exclusion, individual job preferences, a goal of competitive employment, employers are approached with the needs of the individual in mind, provision of

ongoing time-unlimited support, integration within the mental health treatment team, job search begins directly on entry into the IPS programme, and personalised benefits counselling. IPS is typically provided as part of a wider early intervention service, making the disentanglement of the effect on function difficult. Moreover, intervention components of IPS overlap to an extent with SRT and FBT in terms of psychoeducation, problem solving skills, goal formulation and notably a community-based, practical approach to recovery.

We identified three studies reporting on supported employment in early psychosis with no studies identified in relation to the clinical high-risk group. Two IPS studies in first-episode psychosis reported a significant impact on function as measured by participation in employment and reduced utilisation of welfare benefits (Killackey et al., 2019; Killackey, Jackson, & McGorry, 2008). Unlike CBTp and FBT studies discussed in this review, clinical presentation, and the impact of IPS on symptom severity were not reported in these studies. Instead, the studies focused on whether recovery of social and occupational functioning was maintained over time. In particular, these studies focused on whether return to work and gains in educational attainments and were sustained over time when compared to early intervention services where staff are upskilled in vocational recovery. Similarly, a third early psychosis study took education into account, reporting on a supported employment and education intervention, informed by the broader supported employment model and IPS, combined with supported education services (Rosenheck et al., 2017). This intervention was provided in the context of an early intervention service. They report increased participation in work or school, which appears to be mediated, in part, by the supported education service.

Similar to FBT, there was an insufficient number of IPS-based studies from which to generate an intervention-specific effect size. However, as online Supplementary Fig. S3 illustrates, the three studies included in our overall meta-analysis showed significant effects favouring the intervention groups.

Cognitive remediation training (CRT)

CRT is a 'behavioural training-based intervention which aims to improve cognitive processes (attention, memory, executive function, social cognition or metacognition) with the goal of durability and generalisation' ['Cognitive Remediation Experts Workshop (CREW)', Florence, April 2010]. For schizophrenia generally, a meta-analysis of CRT reported an effect size of Cohen's $d = 0.45$ for cognitive performance, $d = 0.42$ for psychosocial functioning and $d = 0.18$ for symptom severity. Wykes, Huddy, Cellard, Mcgurk, and Czobor (2011) further concluded that CRT is more effective when provided in the context of a rehabilitation setting, allowing individuals to put their training into practice (Wykes et al., 2011). Different CRT interventions targeted a variety of perceptual and cognitive skills, including social cognition (e.g. emotion processing or facial affect recognition) with the goal of translating training into improved social and occupational functioning. A meta-analytic investigation of social cognitive training for schizophrenia in 2012 demonstrated moderate to large effects on observer-rated community and institutional function (Cohen's $d = 0.78$) (Kurtz & Richardson, 2012). One criticism of CRT has been the high level of the 1:1 therapy time involved. However, we have reported evidence that significant improvements in both neuropsychological function and social/occupational functioning following a computer-based working memory intervention that required only weekly 1 h 1:1 support (Donohoe et al., 2018).

What is the evidence for impact of CRT on social and occupational functioning in the clinical high-risk and early psychosis groups? Our review identified 10 studies providing a CRT intervention reporting on validated measures of function in these groups. Two studies reported on CRT in the UHR group. Piskulic, Barbato, Liu, and Addington (2015) report significant improvement in function in the intervention group while Choi et al. (2016) report a non-significant impact. Interestingly, both studies were computer-game based with a primary cognitive outcome however varied in terms of the intervention setting and type of functional outcome used. Piskulic et al. (2015) were delivered online and utilised a social functioning measure while Choi et al. (2016) were delivered in a traditional clinic setting and used a global measure of function. This will be considered further in the discussion below.

Five of eight studies in the early psychosis group reported evidence of a significant impact on social and occupational functioning outcomes. Of note, each of these interventions included components such as psychoeducation or a social skills group that scaffolded training e.g. by specifically relating it to greater social involvement (Eack et al., 2009; Eack, Greenwald, Hogarty, & Keshavan, 2010; Lee et al., 2013; Loewy et al., 2016; Ventura et al., 2017).

The remaining three studies in the early psychosis group reported no significant effect of the CRT intervention on psychosocial functioning (Mendella et al., 2015; Østergaard Christensen et al., 2014; Vidarsdottir et al., 2019). In the Østergaard Christensen et al. (2014) study a failure to observe benefits to psychosocial function was despite improvements in symptom severity, cognitive function and self-esteem (Østergaard Christensen et al., 2014). Vidarsdottir and colleagues report no improvement in either symptoms or social functioning (Vidarsdottir et al., 2019). Similarly, Mendella et al. (2015) report improvements in cognitive domains but no impact on psychosocial functioning or symptoms (Mendella et al., 2015). An interpretation of these findings is that although all the above studies found evidence of improved cognitive function following CRT, these benefits were more likely to translate to benefits in social and occupational function when delivered alongside additional components that promoted broader recovery and greater psychosocial engagement. In short, as with CRT interventions delivered in chronic schizophrenia (SZ), CRT in early psychosis is more likely to be beneficial when provided in the context of broader rehabilitation (e.g. early intervention services).

The data from the 10 CRT studies were available for meta-analysis, allowing us to test the significance of this intervention separately. As illustrated in Fig. 2, CRT was associated with modest but significant improvements in social and occupational function when compared to control conditions [SMD = 0.301, 95% CI (0.004–0.599), $p = 0.047$]. As illustrated by Fig. 2, difference in effect sizes reported could not be easily understood in terms of differences in sample type (first-episode/early psychosis groups *v.* UHR groups).

Multi-component psychosocial intervention

The concept, purpose and effectiveness of multi-component early intervention for psychosis services (EIS) has recently been described in a meta-analysis (Correll et al., 2018). As described by Correll et al. (2018) these interventions included the 'core' components of psychopharmacological treatment (with regular medication review) and family psychoeducation/counselling, alongside 'optional' components of CBT, family therapy,

vocational and education counselling, social skills training, crisis management and a crisis response team. The range of intervention components was 4–6 with a mean of 4.8 (0.9) components. Important clinical outcomes in this study were considered as all-cause treatment discontinuation, hospitalisation, total and specific (positive, negative, general and depressive) symptom severity, global functioning and involvement in school or work and quality of life (Correll et al., 2018). The authors report superior outcomes for all 13 meta-analysable outcomes over treatment as usual (TAU) at several time points of treatment with small to moderate effect sizes evident. In terms of social and occupational functioning, seven studies ($n = 1005$) reported global functioning improving significantly more in EIS than TAU with six studies ($n = 1743$) also reporting significantly higher participation in school or work in EIS than TAU.

In our review of psychosocial interventions, we reviewed those studies that estimated the effects on psychosocial function of multi-component psychosocial intervention. Specifically, here, multi-component psychosocial intervention refers to studies which incorporate more than one psychosocial treatment approach from among CBTp, social skills training, family training and psychoeducation, but without the explicit inclusion of a pharmacological intervention, medication review or stipulation of core or fundamental components. In short, although it is acknowledged pharmacotherapy is frequently offered, these multi-component psychosocial interventions, rather than providing a single therapeutic approach, apply several approaches and underlying therapeutic principles with the aim of improving social and occupational functioning. Seven studies were identified under this category (see online Supplementary Table S2), two based on in high-risk samples and five based on individuals with early psychosis. Of the high-risk studies, Albert et al. (2016) found no evidence of improvement, despite observing that low levels of functioning were a consistent predictor of transition to psychosis (Albert et al., 2016). By comparison, Wessels et al. (2015) reported evidence of significant increase in function (as measured by the GAF scale) following a multi-components intervention (Wessels et al., 2015).

In the early psychosis group, four of the five studies report improvement in functioning in early psychosis (Macneil et al., 2012; Palma et al., 2019; Ruggeri et al., 2015; Schlosser et al., 2018). Intervention approaches in this category had the consistent features of adopting a manualised approach to the components provided and selecting individual intervention components based on the specific patients. The flexibility of intervention component selection in particular appears beneficial to individual and group outcomes in terms of psychosocial functioning; heterogeneity between these manualised approaches may present challenges in terms of replication of results and direct comparison between studies.

The data from the seven multi-component psychosocial studies were also available for meta-analysis. Figure 2 illustrates this group was also associated with modest but significant improvements in social and occupational functioning when compared to a control condition [SMD = 0.452, 95% CI (0.061–0.843), $p = 0.023$]. When the non-RCT study (Macneil et al., 2012) in this intervention category was excluded from the analysis the effect size SMD changed to SMD = 0.395) (see online Supplementary Fig. S11).

Meta-analysis by illness stage, length and duration of intervention, and outcome measurement type

Subgroup analyses were performed to compare effect sizes based on diagnosis, length of intervention, number of sessions, control condition, mode of delivery and type of outcome measure (see online Supplementary Figs. S5–S10). When compared for diagnosis (UHR *v.* FEP *v.* early psychosis), the SMD was largest for the early psychosis group [SMD = 0.572, 95% CI (0.129–1.014), $p = 0.011$], followed by the FEP group [SMD = 0.360, 95% CI (0.198–0.521), $p < 0.001$], and the smallest effect size was found for UHR group [SMD = 0.107,95% CI (−0.066 to 0.280), $p < 0.001$]. For length of intervention, studies with duration of 6 months or less were compared to those with duration of greater than 6 months. Effect sizes were larger for studies with a longer duration [SMD = 0.397, 95% CI (0.149–0.645), $p = 0.002$] compared to studies of 6 months or less [SMD = 0.251, 95% CI (0.088–0.415), $p = 0.003$]. Similarly, when compared based on number of sessions, studies with >30 sessions showed a larger effect [SMD = 0.487, 95% CI (0.158–0.816), $p = 0.004$] than those with 30 sessions or less [SMD = 0.225, 95% CI (0.077–0.372), $p = 0.003$]. For control condition, studies that used an active control showed a smaller effect [SMD = 0.258, 95% CI (0.091–0.424), $p = 0.002$] than those that compared the intervention to TAU [SMD = 0.464, 95% CI (0.194–0.733), $p < 0.001$]. For mode of delivery of the intervention, community-based interventions [SMD = 0.376, 95% CI (0.129–0.623), $p = 0.003$] showed a larger effect than clinic-based interventions [SMD = 0.264, 95% CI (0.081–0.447), $p = 0.005$]. Interventions delivered online showed the largest effect size [SMD = 0.497, 95% CI (−0.179 to 1.174), $p = 0.150$], however this effect was not significant and was based on only three studies. Finally, studies were grouped based on type of outcome measure used – we compared measures of general function to more specific measures of function (global function *v.* social function *v.* employment). There was a notable difference in effect size between these groups. Results of this subgroup analysis showed much larger effect sizes for studies that used more specific measures of employment [SMD = 0.611, 95% CI (0.127–1.095), $p = 0.013$] or social functioning [SMD = 0.716, 95% CI (0.372–1.060), $p < 0.001$] compared to global functioning measures [SMD = 0.197, 95% CI (0.049–0.346), $p = 0.009$].

Discussion

This review and meta-analysis focused on psychosocial interventions that sought to improve social and occupational function in the early stages of psychosis, a relatively recent and emerging focus of psychosis research. Previously, psychosocial interventions had focused either solely, or principally on reducing clinical symptoms severity as their endpoint, on the basis that this would be associated with improved functional outcomes. The absence of empirical support for this expectation has in large part informed this wider focus on and targeting of social and occupational function. As reviewed here, studies that have taken up this challenge have been varied in terms of intervention, outcomes measured used, and participants. Notwithstanding this heterogeneity, broad evidence was observed to support the efficacy of psychosocial interventions for improving social and occupational function in the early stages of psychosis.

In addition to this general conclusion, several specific conclusions can also be made. Firstly, our narrative review of the available evidence suggests that delivering psychosocial intervention in community-based (rather than clinic-based settings) settings is a key consideration. Community-based, assertive outreach approaches – irrespective of treatment type – appear to have a greater impact on function in the early psychosis population. Moving from clinic-based interventions towards providing

treatment in the person's usual environment with involvement of key community stakeholders appears a key ingredient for effectiveness and collaborative, patient-centred working. For example, when compared to CBTp studies, where clinical improvement was not necessarily associated with improved social functioning, family-based intervention studies reporting evidence of improvement in social and occupational functioning in the clinical high-risk group tended to also report evidence of improvement in clinical presentation. One possible factor in this difference in social and occupational outcomes was the setting, with family-based interventions more likely to be delivered in the community, outside a traditional clinic setting. As noted above, social recovery orientated CBT, which is employs an assertive outreach approach and is delivered in a community setting was also found to be effective in improving social and occupational functioning (see online Supplementary Fig. S9).

Secondly, a personalised approach to treatment that matches the psychosocial interventions provided to the needs of the individual appears critical to meeting the complex needs of individuals in the early stages of psychosis. Multi-component interventions (both at an early intervention service level and psychosocial intervention level), tailored to the needs of the individual, appear to have greater potential to impact a range of psychosocial treatment targets. Critical to the success of these multi-component interventions would appear to be the capacity to provide these components flexibly in a manner adapted to the changing needs and circumstances of individual.

In estimating the contribution of individual psychosocial intervention types, both treatment intensity and duration were observed to moderate efficacy. As noted in the findings of our meta-analysis, interventions of a 6-month duration or longer or >30 sessions were found to have a greater impact on social and occupational functioning when compared to those 6 months or less or <30 sessions (see online Supplementary table and Figs. S6 and S7).

Similarly, the type of measurement used when considering social and occupational function was observed to significantly influence the size of effect observed, with measures that specifically targeted social functioning and engagement, and employment activity yielding a more sensitive estimate of change following intervention that more global indicators (see online Supplementary Fig. S9).

Furthermore, stage of illness – whether pre or post first diagnosis of psychosis was also observed to impact on the efficacy of treatments. In particular, improvement in psychosocial function following the interventions reviewed was greater for individuals following a diagnosis of psychotic illness (FEP or early psychosis compared to UHR). This evidence may reflect the fact that a further decline in psychosocial function following diagnosis creates a wider target for the interventions considered here to have an effect. If true, we speculate that this may not mean that interventions targeting psychosocial function are less effective in the UHR or FEP group, but simply that level of social and occupational function continues to decrease during this time, thus creating a larger window of deficits in which to demonstrate recovery. This finding is considered in the context of the review limitation of the variability in defining stage of illness across studies, the impact on recruitment and inclusion criteria of individual studies, and the clinical heterogeneity of the UHR group.

As noted, a review and meta-analysis on the impact of psychosocial intervention on validated measures of function is an emerging area of research in the area of early psychosis. This study, although providing preliminary evidence of effectiveness of psychosocial intervention in this area, is not without its limitations. Firstly, we note the heterogeneity in study design and methodologies in this area of research. The quality evaluation scale (Rokita et al., 2018) employed for this review while meeting quality assurance standards did not account for variation in randomisation and blinding and this should be considered in future reviews and meta-analyses.

A second consideration is the heterogeneity of validated measures of function ranging from global assessments to individual measure of function. The authors conclude how they measure function and considering social and occupational functioning as a primary outcome in the early psychosis group is a priority consideration in future study design. This will have potential impact on study replicability, and comparison of high-quality psychosocial intervention studies at a meta-analytical level.

Thirdly, the authors also acknowledge the lack of available data in the included studies in terms of the acceptability of the intervention to the participants and also the adherence to therapy during individual studies. Monitoring adherence to TAU, including pharmacotherapy, is also vital in future study design. These are priority considerations for future research and are likely not only to contribute to the quality of future studies but also the translation to clinical practice.

In conclusion, the increased emphasis on the value of targeting and treating social and occupational function in the early treatment of psychosis appears to be well founded. As reviewed here, there is evidence that many, but not all, psychosocial interventions are associated with improvements in these areas. We emphasise that the findings from two of the included intervention groups (FBT and IPS) are exploratory in nature due to the small number of studies included. However, we highlight that CRT, multi-component psychosocial intervention and CBT (with an emphasis on assertive outreach) emerge as providing robust evidence for clinical implementation in the early psychosis group. Providing these as part of multi-component interventions in community-based settings remains an important need for this cohort. Supporting the recent progress in increasing the availability of these interventions remains a key priority.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S003329172100341X.

Financial support. This work was funded by the Irish Health Research Board as part of the collaborative doctoral award in Youth Mental Health [YOULEAD] (HRB grant number: CDA-2018-001).

Conflict of interest. None to declare.

References

Addington, J., Epstein, I., Liu, L., French, P., Boydell, K. M., & Zipursky, R. B. (2011). A randomized controlled trial of cognitive behavioral therapy for individuals at clinical high risk of psychosis. *Schizophrenia Research, 125* (1), 54–61. doi: 10.1016/j.schres.2010.10.015

Albert, N., Glenthøj, L. B., Melau, M., Jensen, H., Hjorthøj, C., & Nordentoft, M. (2016). Course of illness in a sample of patients diagnosed with a schizotypal disorder and treated in a specialized early intervention setting. Findings from the 3.5 year follow-up of the OPUS II study. *Schizophrenia Research, 182*, 24–30. doi: 10.1016/j.schres.2016.10.013

Bechdolf, A., Wagner, M., Veith, V., Ruhrmann, S., Pukrop, R., Brockhaus-Dumke, A., … Klosterkotter, J. (2007). Randomized controlled multicentre trial of cognitive behaviour therapy in the early initial prodromal

state: Effects on social adjustment post treatment. *Early Intervention in Psychiatry*, *1*(1), 71–78. doi: 10.1111/j.1751-7893.2007.00013.x

Bighelli, I., Salanti, G., Huhn, M., Schneider-Thoma, J., Krause, M., Reitmeir, C., … Leucht, S. (2018). Psychological interventions to reduce positive symptoms in schizophrenia: Systematic review and network meta-analysis. *World Psychiatry*, *17*(3), 316–329. doi: 10.1002/wps.20577

Borenstein, M., Hedges, L., Higgins, J., & Rothstein, H. (2011). *Introduction to meta-analysis*. Englewood, NJ: Biostat.

Borenstein, M., Hedges, L., Higgins, J., & Rothstein, H. (2013). *Comprehensive meta-analysis version 3*. Englewood, NJ: Biostat.

Choi, J., Corcoran, C. M., Fiszdon, J. M., Stevens, M., Javitt, D. C., Deasy, M., … Pearlson, G. D. (2016). Pupillometer-based neurofeedback cognitive training to improve processing speed and social functioning in individuals at clinical high risk for psychosis. *Psychiatric Rehabilitation Journal*, *40*(1), 33–42. doi: 10.1037/prj0000217

Correll, C. U., Galling, B., Pawar, A., Krivko, A., Bonetto, C., Ruggeri, M., … Kane, J. M. (2018). Comparison of early intervention services vs treatment as usual for early-phase psychosis. *Journal of American Medical Association Psychiatry*, *75*(6), 555–565. doi: 10.1001/jamapsychiatry.2018.0623

Donohoe, G., Dillon, R., Hargreaves, A., Mothersill, O., Castorina, M., Furey, E., … Robertson, I. H. (2018). Effectiveness of a low support, remotely accessible, cognitive remediation training programme for chronic psychosis: Cognitive, functional and cortical outcomes from a single blind randomised controlled trial. *Psychological Medicine*, *48*(5), 751–764. doi: 10.1017/s0033291717001982

Duval, S., & Tweedie, R. (2000). Trim and fill: A simple funnel-plot-based method of testing and adjusting for publication bias in meta-analysis. *Biometrics*, *56*(2), 455–463. doi: 10.1111/j.0006-341x.2000.00455.x

Eack, S. M., Greenwald, D. P., Hogarty, S. S., Cooley, S. J., DiBarry, A. L., Montrose, D. M., & Keshavan, M. S. (2009). Cognitive enhancement therapy for early-course schizophrenia: Effects of a two-year randomized controlled trial. *Psychiatric Services*, *60*(11), 1468–1476. doi: 10.1176/appi.ps.60.11.1468

Eack, S. M., Greenwald, D. P., Hogarty, S. S., & Keshavan, M. S. (2010). One-year durability of the effects of cognitive enhancement therapy on functional outcome in early schizophrenia. *Schizophrenia Research*, *120* (1–3), 210–216. doi: 10.1016/j.schres.2010.03.042

Egger, M., Smith, G. D., Schneider, M., & Minder, C. (1997). Bias in meta-analysis detected by a simple, graphical test. *British Medical Journal (Clinical Research Ed.)*, *315*(7109), 629–634. doi: 10.1136/bmj.315.7109.629

Fowler, D., Hodgekins, J., & French, P. (2019). Social recovery therapy in improving activity and social outcomes in early psychosis: Current evidence and longer term outcomes. *Schizophrenia Research*, *203*, 99–104. doi: 10.1016/j.schres.2017.10.006

Fowler, D., Hodgekins, J., French, P., Marshall, M., Freemantle, N., McCrone, P., … Birchwood, M. (2018). Social recovery therapy in combination with early intervention services for enhancement of social recovery in patients with first-episode psychosis (SUPEREDEN3): A single-blind, randomised controlled trial. *The Lancet Psychiatry*, *5*(1), 41–50. doi: 10.1016/S2215-0366(17)30476-5

Fowler, D., Hodgekins, J., Painter, M., Reilly, T., Crane, C., Macmillan, I., … Jones, P. B. (2009). Cognitive behaviour therapy for improving social recovery in psychosis: A report from the ISREP MRC trial platform study (improving social recovery in early psychosis). *Psychological Medicine*, *39* (10), 1627–1636. doi: 10.1017/S0033291709005467

Fusar-Poli, P., Rocchetti, M., Sardella, A., Avila, A., Brandizzi, M., Caverzasi, E., … Mcguire, P. (2015). Disorder, not just state of risk: Meta-analysis of functioning and quality of life in people at high risk of psychosis. *British Journal of Psychiatry*, *207*(3), 198–206. doi: 10.1192/bjp.bp.114.157115

Granö, N., Karjalainen, M., Ranta, K., Lindgren, M., Roine, M., & Therman, S. (2016). Community-oriented family-based intervention superior to standard treatment in improving depression, hopelessness and functioning among adolescents with any psychosis-risk symptoms. *Psychiatry Research*, *237*, 9–16. doi: 10.1016/j.psychres.2016.01.037

Green, M. F. (2016). Impact of cognitive and social cognitive impairment on functional outcomes in patients with schizophrenia. *Journal of Clinical Psychiatry*, *77*(Suppl 2), 8–11. doi: 10.4088/JCP.14074su1c.02

Hodgekins, J., Birchwood, M., Christopher, R., Marshall, M., Coker, S., Everard, L., … Fowler, D. (2015). Investigating trajectories of social recovery in individuals with first-episode psychosis: A latent class growth analysis. *British Journal of Psychiatry: The Journal of Mental Science*, *207*(6), 536–543. doi: 10.1192/bjp.bp.114.153486

Ising, H. K., Kraan, T. C., Rietdijk, J., Dragt, S., Klaassen, R. M., Boonstra, N., Nieman, D. H., … Van der Gaag, M. (2016). Four-year follow-up of cognitive behavioral therapy in persons at ultra-high risk for developing psychosis: The Dutch early detection intervention evaluation (EDIE-NL) trial. *Schizophrenia Bulletin*, *42*(5), 1243–1252. doi: 10.1093/schbul/sbw018

Jackson, H. J., McGorry, P. D., Killackey, E., Bendall, S., Allott, K., Dudgeon, P., … Harrigan, S. (2007). Acute-phase and 1-year follow-up results of a randomized controlled trial of CBT versus befriending for first-episode psychosis: The ACE project. *Psychological Medicine*, *38*(5), 725–735. doi: 10.1017/S0033291707002061

Jones, C., Hacker, D., Meaden, A., Cormac, I., Irving, C. B., Xia, J., … Chen, J. (2018). Cognitive behavioural therapy plus standard care versus standard care plus other psychosocial treatments for people with schizophrenia. *Cochrane Database of Systematic Reviews*, *11*(11), CD008712. doi: 10.1002/14651858.cd008712.pub3

Jordan, G., Lutgens, D., Joober, R., Lepage, M., Iyer, S. N., & Malla, A. (2014). The relative contribution of cognition and symptomatic remission to functional outcome following treatment of a first episode of psychosis. *Journal of Clinical Psychiatry*, *75*(6), 566–557. doi: 10.4088/JCP.13m08606

Jordan, G., Veru, F., Lepage, M., Joober, R., Malla, A., & Iyer, S. N. (2018). Pathways to functional outcomes following a first episode of psychosis: The roles of premorbid adjustment, verbal memory and symptom remission. *Australian and New Zealand Journal of Psychiatry*, *52*(8), 793–803. doi: 10.1177/0004867417747401

Killackey, E., Allott, K., Jackson, H. J., Scutella, R., Tseng, Y. P., Borland, J., … Cotton, S. M. (2019). Individual placement and support for vocational recovery in first-episode psychosis: Randomised controlled trial. *British Journal of Psychiatry*, *214*(2), 76–82. doi: 10.1192/bjp.2018.191

Killackey, E., Jackson, H. J., & McGorry, P. D. (2008). Vocational intervention in first-episode psychosis: Individual placement and support v. treatment as usual. *British Journal of Psychiatry*, *193*(2), 114–120. doi: 10.1192/bjp.bp.107.043109

Kurtz, M. M., & Richardson, C. L. (2012). Social cognitive training for schizophrenia: A meta-analytic investigation of controlled research. *Schizophrenia Bulletin*, *38*(5), 1092–1104. doi: 10.1093/schbul/sbr036

Laws, K. R., Darlington, N., Kondel, T. K., Mckenna, P. J., & Jauhar, S. (2018). Cognitive behavioural therapy for schizophrenia – outcomes for functioning, distress and quality of life: A meta-analysis. *Biomedicine Central Psychology*, *6*(1), 32–42. doi: 10.1186/s40359-018-0243-2

Lee, R. S. C., Redoblado-Hodge, M. A., Naismith, S. L., Hermens, D. F., Porter, M. A., & Hickie, I. B. (2013). Cognitive remediation improves memory and psychosocial functioning in first-episode psychiatric out-patients. *Psychological Medicine*, *43*(6), 1161. doi: 10.1017/s0033291712002127

Loewy, R., Fisher, M., Schlosser, D. A., Biagianti, B., Stuart, B., Mathalon, D. H., & Vinogradov, S. (2016). Intensive auditory cognitive training improves verbal memory in adolescents and young adults at clinical high risk for psychosis. *Schizophrenia Bulletin*, *42*(suppl 1), 118–126. doi: 10.1093/schbul/sbw009

Macneil, C. A., Hasty, M., Cotton, S., Berk, M., Hallam, K., Kader, L., … Conus, P. (2012). Can a targeted psychological intervention be effective for young people following a first manic episode? Results from an 18-month pilot study. *Early Intervention in Psychiatry*, *6*(4), 380–388. doi: 10.1111/j.1751-7893.2011.00336.x

Malla, A., & Mcgorry, P. (2019). Early intervention in psychosis in young people: A population and public health perspective. *American Journal of Public Health*, *109*(3), 181–184. doi: 10.2105/ajph.2019.305018

Mcfarlane, W. R., Levin, B., Travis, L., Lucas, F. L., Lynch, S., Verdi, M., … Spring, E. (2015). Clinical and functional outcomes after 2 years in the early detection and intervention for the prevention of psychosis multisite effectiveness trial. *Schizophrenia Bulletin*, *41*(1), 30–43. doi: 10.1093/schbul/sbu108

Mendella, P. D., Burton, C. Z., Tasca, G. A., Roy, P., St. Louis, L., & Twamley, E. W. (2015). Compensatory cognitive training for people with first-episode schizophrenia: Results from a pilot randomized controlled trial. *Schizophrenia Research*, *162*(1–3), 108–111. doi: 10.1016/j.schres.2015.01.016

Miklowitz, D. J., O'Brien, M. P., Schlosser, D. A., Addington, J., Candan, K. A., Marshall, C., … Cannon, T. D. (2014). Family-focused treatment for adolescents and young adults at high risk for psychosis: Results of a randomized trial. *Journal of the American Academy of Child & Adolescent Psychiatry*, *53*(8), 848–858. doi: 10.1016/j.jaac.2014.04.020

Morrison, A. P., French, P., Walford, L., Lewis, S. W., Kilcommons, A., Green, J., … Bentall, R. P. (2004). Cognitive therapy for the prevention of psychosis in people at ultra-high risk. *British Journal of Psychiatry*, *185*(4), 291–297. doi: 10.1192/bjp.185.4.291

National institute for Health and Care Excellence (NICE) (2014) Psychosis and Schizophrenia in Adults: Prevention and Management, National Clinical Practice Guidelines (CG178). Retrieved from https://www.nice.org.uk/guidance/cg178/evidence/full-guideline-490503565.

National institute for Health and Care Excellence (NICE) (2015) Quality Standards for Mental Health Early Intervention Service Provision for Adults with Psychosis or Schizophrenia. Retrieved from https://www.nice.org.uk/guidance/qs80.

Østergaard Christensen, T., Vesterager, L., Krarup, G., Olsen, B. B., Melau, M., Gluud, C., & Nordentoft, M. (2014). Cognitive remediation combined with an early intervention service in first episode psychosis. *Acta Psychiatrica Scandinavica*, *130*(4), 300–310. doi: 10.1111/acps.12287

Palma, C., Farriols, N., Frías, A., Cañete, J., Gomis, O., Fernández, M., … Signo, S. (2019). Randomized controlled trial of cognitive-motivational therapy program (PIPE) for the initial phase of schizophrenia: Maintenance of efficacy at 5-year follow up. *Psychiatry Research*, *273*, 586–594. doi: 10.1016/j.psychres.2019.01.084

Penn, D. L., Uzenoff, S. R., Perkins, D, Mueser, K. T., Hamer, R, Waldheter, E, … Cook, L. (2011). A pilot investigation of the Graduated Recovery Intervention Program (GRIP) for first episode psychosis. *Schizophrenia Research*, *125*(2-3), 247–256. doi: 10.1016/j.schres.2010.08.006

Piskulic, D., Barbato, M., Liu, L., & Addington, J. (2015). Pilot study of cognitive remediation therapy on cognition in young people at clinical high risk of psychosis. *Psychiatry Research*, *225*(1–2), 93–98. doi: 10.1016/j.psychres.2014.10.021

Ramsay, C. E., Broussard, B., Goulding, S. M., Cristofaro, S., Hall, D., Kaslow, N. J., … Compton, M. T. (2011). Life and treatment goals of individuals hospitalized for first-episode nonaffective psychosis. *Psychiatry Research*, *189*(3), 344–348. doi: 10.1016/j.psychres.2011.05.039

Rinaldi, M., Killackey, E., Smith, J., Shepherd, G., Singh, S. P., & Craig, T. (2010). First episode psychosis and employment: A review. *International Review of Psychiatry*, *22*(2), 148–162. doi: 10.3109/09540261003661825

Rokita, K. I., Dauvermann, M. R., & Donohoe, G. (2018). Early life experiences and social cognition in major psychiatric disorders: A systematic review. *European Psychiatry*, *53*, 123–133. doi: 10.1016/j.eurpsy.2018.06.006

Rosenheck, R., Mueser, K. T., Sint, K., Lin, H., Lynde, D. W., Glynn, S. M., … Kane, J. M. (2017). Supported employment and education in comprehensive, integrated care for first episode psychosis: Effects on work, school, and disability income. *Schizophrenia Research*, *182*, 120–128. doi: 10.1016/j.schres.2016.09.024

Ruggeri, M., Bonetto, C., Lasalvia, A., Fioritti, A., de Girolamo, G., Santonastaso, P., … Group, G. U. (2015). Feasibility and effectiveness of a multi-element psychosocial intervention for first-episode psychosis: Results from the cluster-randomized controlled GET UP PIANO trial in a catchment area of 10 million inhabitants. *Schizophrenia Bulletin*, *41*(5), 1192–1203. doi: 10.1093/schbul/sbv058

Santesteban-Echarri, O., Paino, M., Rice, S., González-Blanch, C., Mcgorry, P., Gleeson, J., & Alvarez-Jimenez, M. (2017). Predictors of functional recovery in first-episode psychosis: A systematic review and meta-analysis of longitudinal studies. *Clinical Psychology Review*, *58*, 59–75. doi: 10.1016/j.cpr.2017.09.007

Schlosser, D. A., Campellone, T. R., Truong, B., Etter, K., Vergani, S., Komaiko, K., & Vinogradov, S. (2018). Efficacy of PRIME, a mobile App intervention designed to improve motivation in young people with schizophrenia. *Schizophrenia Bulletin*, *44*(5), 1010–1020. doi: 10.1093/schbul/sby078

Stain, H. J., Bucci, S., Baker, A. L., Carr, V., Emsley, R., Halpin, S., … Startup, M. (2016). A randomised controlled trial of cognitive behaviour therapy versus non-directive reflective listening for young people at ultra high risk of developing psychosis: The detection and evaluation of psychological therapy (DEPTh) trial. *Schizophrenia Research*, *176*(2–3), 212–219. doi: 10.1016/j.schres.2016.08.008

Stouten, L. H., Veling, W., Laan, W., Van Der Helm, M., & Van Der Gaag, M. (2017). Psychosocial functioning in first-episode psychosis and associations with neurocognition, social cognition, psychotic and affective symptoms. *Early Intervention in Psychiatry*, *11*(1), 23–36. doi: 10.1111/eip.12210

Velthorst, E., Koeter, M., Van Der Gaag, M., Nieman, D. H., Fett, A. K. J., Smit, F., … De Haan, L. (2015). Adapted cognitive–behavioural therapy required for targeting negative symptoms in schizophrenia: Meta-analysis and meta-regression. *Psychological Medicine*, *45*(3), 453–465. doi: 10.1017/s0033291714001147

Ventura, J., Subotnik, K. L., Gretchen-Doorly, D., Casaus, L., Boucher, M., Medalia, A., … Nuechterlein, K. H. (2017). Cognitive remediation can improve negative symptoms and social functioning in first-episode schizophrenia: A randomized controlled trial. *Schizophrenia Research*, *203*, 24–31. doi: 10.1016/j.schres.2017.10.005

Vidarsdottir, O. G., Roberts, D. L., Twamley, E. W., Gudmundsdottir, B., Sigurdsson, E., & Magnusdottir, B. B. (2019). Integrative cognitive remediation for early psychosis: Results from a randomized controlled trial. *Psychiatry Research*, *273*, 690–698. doi: 10.1016/j.psychres.2019.02.007

Waghorn, G., Saha, S., Harvey, C., Morgan, V. A., Waterreus, A., Bush, R., … Mcgrath, J. J. (2012). 'earning and learning' in those with psychotic disorders: The second Australian national survey of psychosis. *Australian & New Zealand Journal of Psychiatry*, *46*(8), 774–785. doi: 10.1177/0004867412452015

Wessels, H., Wagner, M., Frommann, I., Berning, J., Pützfeld, V., Janssen, B., … Bechdolf, A. (2015). Neuropsychological functioning as a predictor of treatment response to psychoeducational, cognitive behavioral therapy in people at clinical high risk of first episode psychosis. *Psychiatrische Praxis*, *42*(6), 313–319. doi: 10.1055/s-0035-1552713

Wykes, T., Huddy, V., Cellard, C., Mcgurk, S. R., & Czobor, P. (2011). A meta-analysis of cognitive remediation for schizophrenia: Methodology and effect sizes. *American Journal of Psychiatry*, *168*(5), 472–485. doi: 10.1176/appi.ajp.2010.10060855

Wykes, T., Newton, E., Landau, S., Rice, C., Thompson, N., & Frangou, S. (2007). Cognitive remediation therapy (CRT) for young early onset patients with schizophrenia: an exploratory randomized controlled trial. *Schizophrenia Research*, *94*(1-3), 221–230. doi: 10.1016/j.schres.2007.03.030

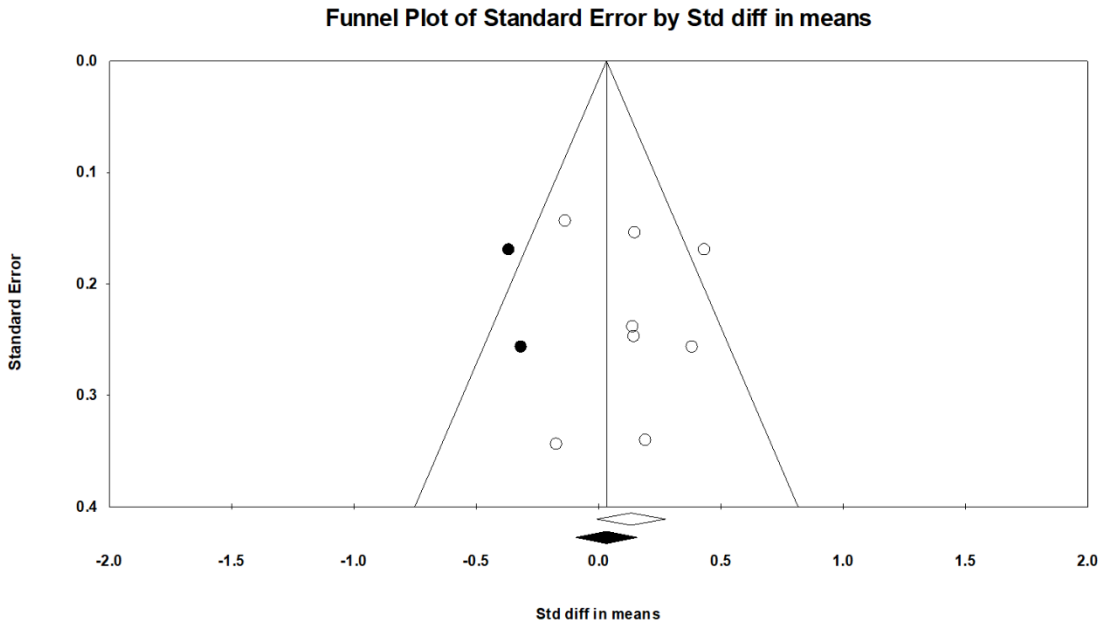
Appendix C Supplementary materials (study 1)

Supplementary Table S1. Description of psychosocial functioning measures used across intervention studies

Measure	Scoring	Description
Global (social and occupational) functioning measures		
Global Assessment of Functioning (GAF)	Scale: 0-100, higher scores indicate better function	Measures social, occupational, and psychological functioning
Social and Occupational Functioning Assessment Scale (SOFAS)	Scale: 0-100, higher scores indicate better function	Measures social, occupational, or school functioning
Social Functioning Scale (SFS)	Scale: 55-135, 79 item questionnaire, 7 subscales summed for total score, higher scores indicate better function	Measures social engagement/withdrawal, interpersonal behaviour, pro-social activities recreation, independence-competence, independence-performance, employment/occupation.
Social Adjustment Scale (SAS)	Scale: 0-5, 52 item questionnaire, lower scores indicate better function	Measures work, household, social activities/leisure, physical well-being, general adjustment summary score
Role Functioning Scale (RFS)	Scale: 4-28, 4 subscales rated 1-7, subscales summed for total score, higher scores indicate better function	Measures work productivity, independent living, immediate social network, and extended social network
Personal and Social Performance Scale (PSP)	Scale: 0-100, higher scores indicate better function	Measures socially useful activities including work and study, personal and social relationships, elf-care, and disturbing and aggressive behaviour
Life Skills Profile (LSP-39)	Scale: 38-156, 39 item questionnaire, lower scores indicate better function	Measures communication, social contact, non-turbulence, self-care, and responsibility
Time Use Survey (TUS)	Hours per week of structured activity	Structured activity includes paid and voluntary employment, education and training, childcare, housework and chores, leisure and sports, socialising.
Functional capacity measures		
UCSD Performance-based Skills Assessment - Brief (UPSA-B)	Scale: 0-100, higher scores indicate better function	Measures ability to perform various tasks related to everyday functioning (e.g., communicating by telephone, counting money, paying bills)
Social functioning measures		
Social Behaviour Schedule (SBS)	Scale: 0-84, 21 item questionnaire, lower scores indicate better function	Measures antisocial behaviour, depressed behaviour, social withdrawal and thought disturbance.
Global Functioning: Social Scale (GFS)	Scale: 1-10, higher scores indicate better function	Measures quantity and quality of peer relationships, level of peer conflict, age-appropriate intimate relationships, and involvement with family members
UCLA Social Attainment Survey	Scale: 0-5, higher scores indicate better function	Measures peer relationships, leadership in peer relationships, dating history, sexual experience, outside activities, and participation in organizations

Supplementary Table S2. Heterogeneity analysis

Fixed effect analysis		**Heterogeneity**				**Tau**			
Group	**No. of studies**	**Q-value**	**df (Q)**	***p*-value**	**I-squared**	**Tau-Squared**	**Standard Error**	**Variance**	**Tau**
CBT	8	8·448	7·000	0·295	17·137	0·009	0·028	0·001	0·095
CRT	10	26·580	9·000	0·002	66·139	0·148	0·109	0·012	0·384
MCI	7	29·859	6·000	0·000	79·906	0·211	0·177	0·031	0·459
SE	3	6·869	2·000	0·032	70·882	0·122	0·188	0·035	0·349
FBI	3	9·994	2·000	0·007	79·988	0·168	0·216	0·047	0·410
Overall	31	88·918	30·000	0·000	66·261	0·095	0·042	0·002	0308



Duval and Tweedie's trim and fill

		Fixed Effects			Random Effects			Q Value
	Studies Trimmed	Point Estimate	Lower Limit	Upper Limit	Point Estimate	Lower Limit	Upper Limit	
Observed values		0.13246	-0.00893	0.27385	0.13893	-0.02139	0.29924	8.44767
Adjusted values	2	0.03201	-0.09390	0.15792	0.04056	-0.14594	0.22707	17.84318

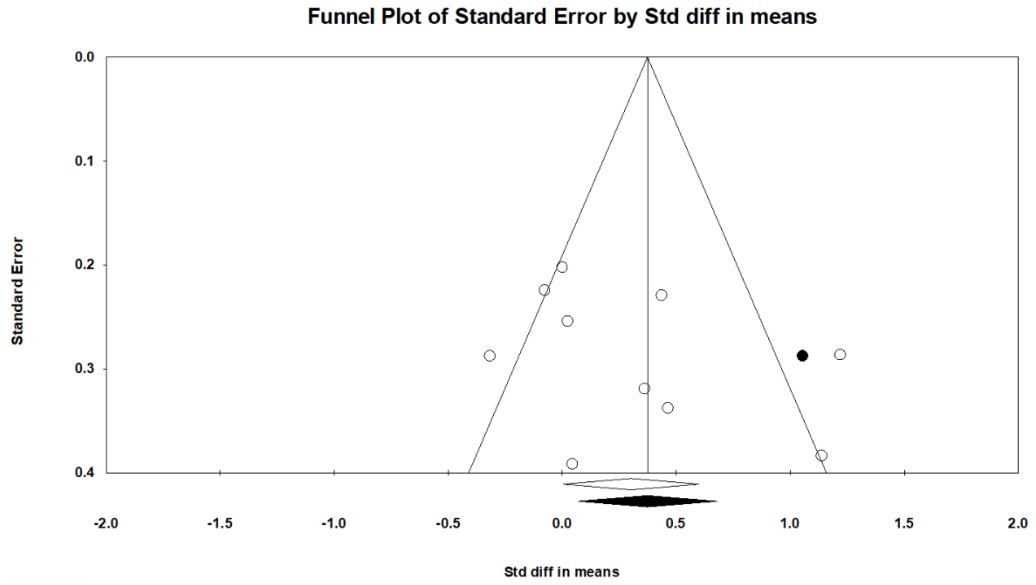
Classic fail-safe N

Z-value for observed studies	1.86229
P-value for observed studies	0.06256
Alpha	0.05000
Tails	2.00000
Z for alpha	1.95996
Number of observed studies	8.00000
Number of missing studies that would bring p-value to > alpha	0.00000

Egger's regression intercept

Intercept	0.43373
Standard error	1.37973
95% lower limit (2-tailed)	-2.94235
95% upper limit (2-tailed)	3.80980
t-value	0.31436
df	6.00000
P-value (1-tailed)	0.38195
P-value (2-tailed)	0.76389

Supplementary Figure S1. Publication bias: CBT



Duval and Tweedie's trim and fill

		Fixed Effects			Random Effects			Q Value
	Studies Trimmed	Point Estimate	Lower Limit	Upper Limit	Point Estimate	Lower Limit	Upper Limit	
Observed values		0.25011	0.08143	0.41880	0.30145	0.00358	0.59931	26.57963
Adjusted values	0	0.25011	0.08143	0.41880	0.30145	0.00358	0.59931	26.57963

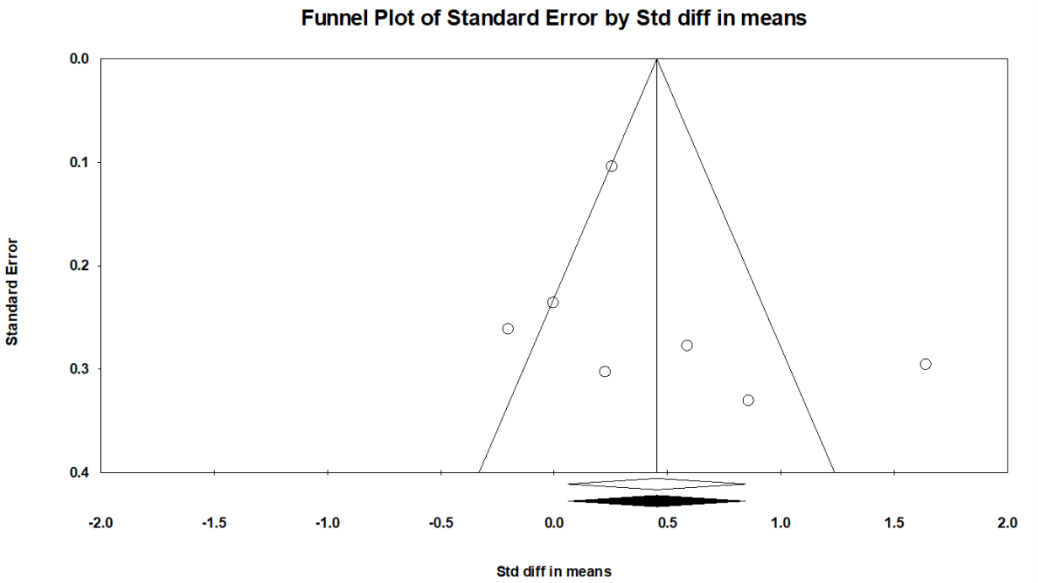
Classic fail-safe N

Z-value for observed studies	3.28378
P-value for observed studies	0.00102
Alpha	0.05000
Tails	2.00000
Z for alpha	1.95996
Number of observed studies	10.00000
Number of missing studies that would bring p-value to > alpha	19.00000

Egger's regression intercept

Intercept	3.16246
Standard error	2.50096
95% lower limit (2-tailed)	-2.60475
95% upper limit (2-tailed)	8.92967
t-value	1.26450
df	8.00000
P-value (1-tailed)	0.12082
P-value (2-tailed)	0.24164

Supplementary Figure S2. Publication bias: CRT



Duval and Tweedie's trim and fill

		Fixed Effects			Random Effects			Q Value
	Studies Trimmed	Point Estimate	Lower Limit	Upper Limit	Point Estimate	Lower Limit	Upper Limit	
Observed values		0.33657	0.18617	0.48698	0.45222	0.06116	0.84327	29.85897
Adjusted values	0	0.33657	0.18617	0.48698	0.45222	0.06116	0.84327	29.85897

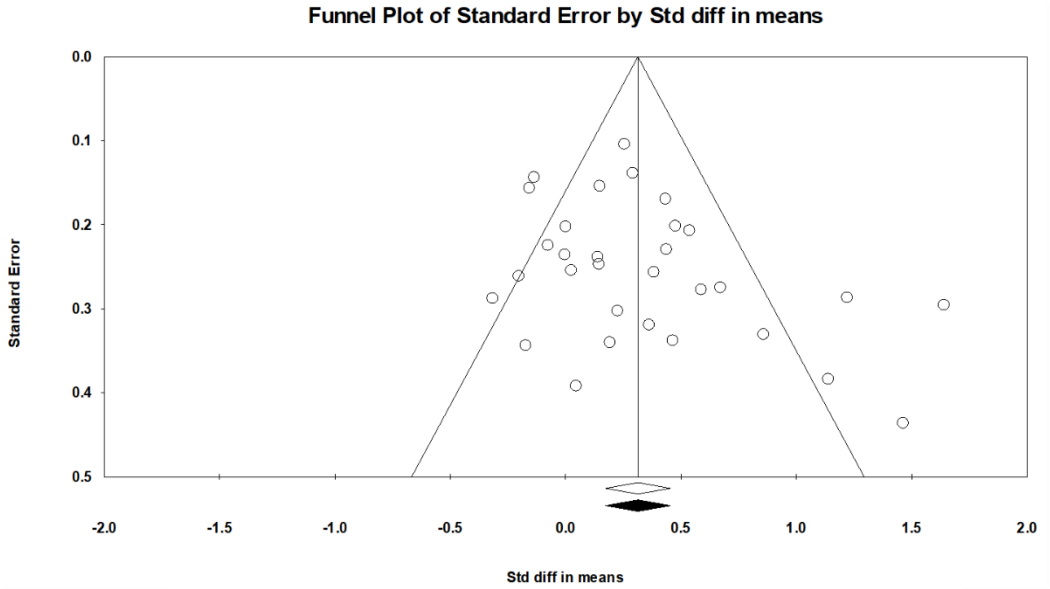
Classic fail-safe N

Z-value for observed studies	4.77923
P-value for observed studies	0.00000
Alpha	0.05000
Tails	2.00000
Z for alpha	1.95996
Number of observed studies	7.00000
Number of missing studies that would bring p-value to > alpha	35.00000

Egger's regression intercept

Intercept	1.65282
Standard error	1.98303
95% lower limit (2-tailed)	-3.44471
95% upper limit (2-tailed)	6.75035
t-value	0.83348
df	5.00000
P-value (1-tailed)	0.22128
P-value (2-tailed)	0.44255

Supplementary Figure S3. Publication bias: MCI



Duval and Tweedie's trim and fill

		Fixed Effects			Random Effects			Q Value
	Studies Trimmed	Point Estimate	Lower Limit	Upper Limit	Point Estimate	Lower Limit	Upper Limit	
Observed values		0.25264	0.17615	0.32912	0.31259	0.17236	0.45281	88.91812
Adjusted values	0	0.25264	0.17615	0.32912	0.31259	0.17236	0.45281	88.91812

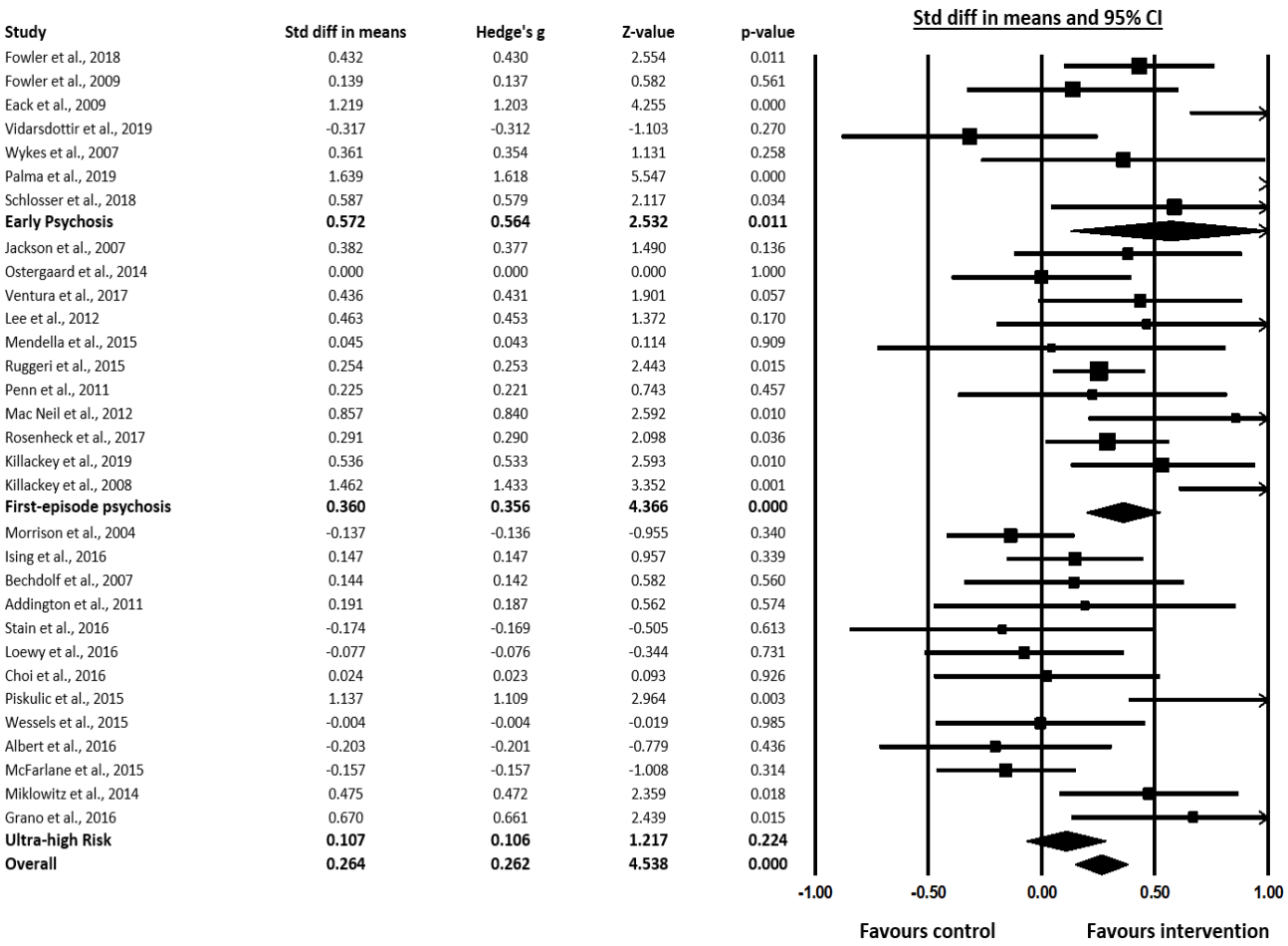
Classic fail-safe N

Z-value for observed studies	7.20746
P-value for observed studies	0.00000
Alpha	0.05000
Tails	2.00000
Z for alpha	1.95996
Number of observed studies	31.00000
Number of missing studies that would bring p-value to > alpha	389.00000

Egger's regression intercept

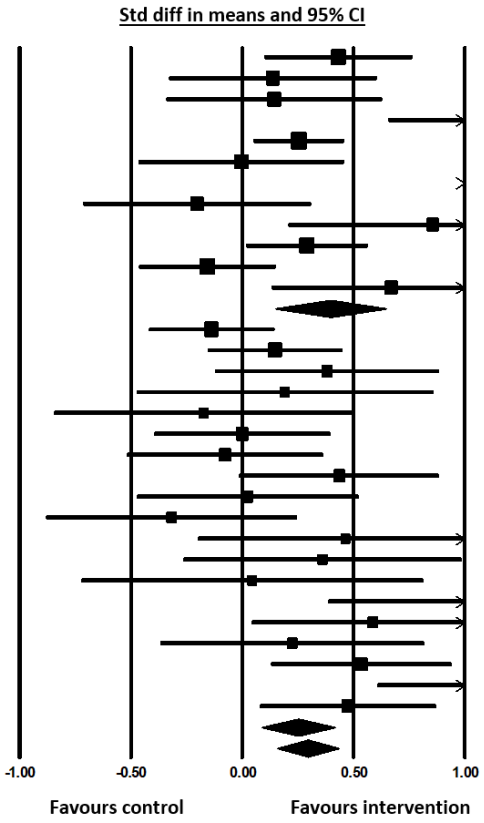
Intercept	1.67927
Standard error	0.84428
95% lower limit (2-tailed)	-0.04747
95% upper limit (2-tailed)	3.40602
t-value	1.98900
df	29.00000
P-value (1-tailed)	0.02810
P-value (2-tailed)	0.05621

Supplementary Figure S4. Publication bias: overall psychosocial interventions



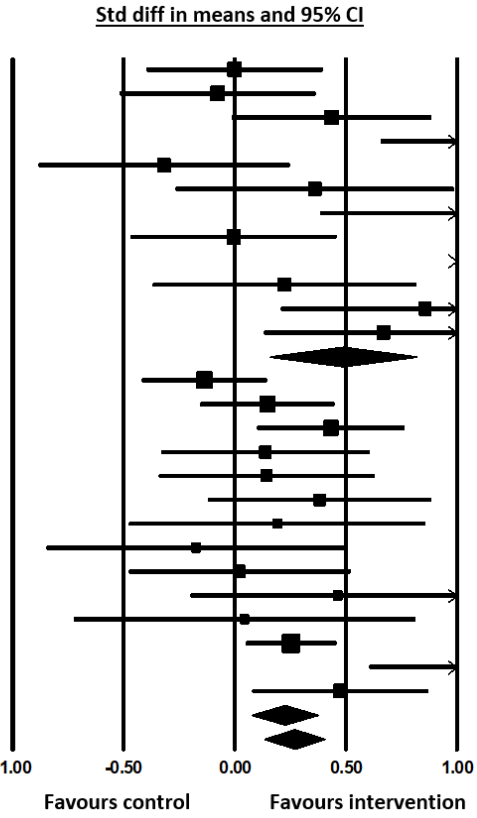
Supplementary Figure S5. Forest plot of overall subgroup analysis grouped by diagnosis

Study	length of intervention (months)	Std diff in means	Hedge's g	Z-value	p-value
Fowler et al., 2018	9	0.432	0.430	2.554	0.011
Fowler et al., 2009	9	0.139	0.137	0.582	0.561
Bechdolf et al., 2007	12	0.144	0.142	0.582	0.560
Eack et al., 2009	24	1.219	1.203	4.255	0.000
Ruggeri et al., 2015	9	0.254	0.253	2.443	0.015
Wessels et al., 2015	12	-0.004	-0.004	-0.019	0.985
Palma et al., 2019	12	1.639	1.618	5.547	0.000
Albert et al., 2016	36	-0.203	-0.201	-0.779	0.436
Mac Neil et al., 2012	18	0.857	0.840	2.592	0.010
Rosenheck et al., 2017	24	0.291	0.290	2.098	0.036
McFarlane et al., 2015	12	-0.157	-0.157	-1.008	0.314
Grano et al., 2016	12	0.670	0.661	2.439	0.015
> 6 months		**0.397**	**0.393**	**3.134**	**0.002**
Morrison et al., 2004	6	-0.137	-0.136	-0.955	0.340
Ising et al., 2016	6	0.147	0.147	0.957	0.339
Jackson et al., 2007	3.5	0.382	0.377	1.490	0.136
Addington et al., 2011	6	0.191	0.187	0.562	0.574
Stain et al., 2016	6	-0.174	-0.169	-0.505	0.613
Ostergaard et al., 2014	4	0.000	0.000	0.000	1.000
Loewy et al., 2016	2	-0.077	-0.076	-0.344	0.731
Ventura et al., 2017	6	0.436	0.431	1.901	0.057
Choi et al., 2016	2	0.024	0.023	0.093	0.926
Vidarsdottir et al., 2019	3	-0.317	-0.312	-1.103	0.270
Lee et al., 2012	2.5	0.463	0.453	1.372	0.170
Wykes et al., 2007	3	0.361	0.354	1.131	0.258
Mendella et al., 2015	3	0.045	0.043	0.114	0.909
Piskulic et al., 2015	3	1.137	1.109	2.964	0.003
Schlosser et al., 2018	3	0.587	0.579	2.117	0.034
Penn et al., 2011	3	0.225	0.221	0.743	0.457
Killackey et al., 2019	6	0.536	0.533	2.593	0.010
Killackey et al., 2008	6	1.462	1.433	3.352	0.001
Miklowitz et al., 2014	6	0.475	0.472	2.359	0.018
≤ 6 months		**0.251**	**0.248**	**3.011**	**0.003**
Overall		**0.295**	**0.292**	**4.239**	**0.000**



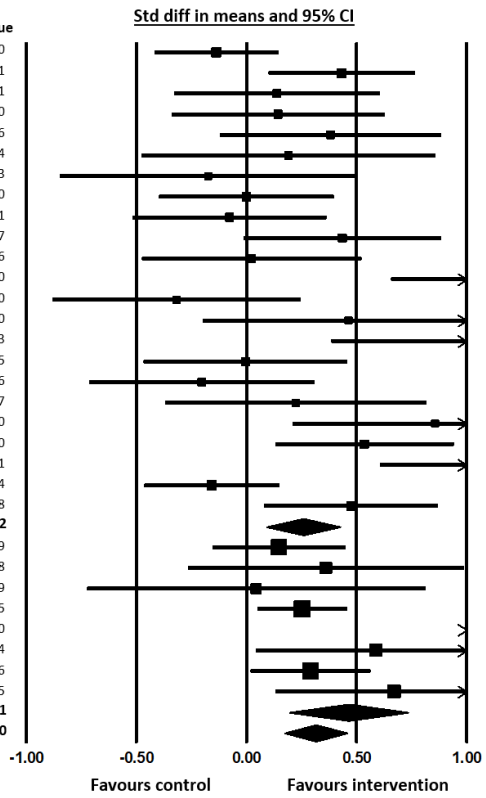
Supplementary Figure S6. Forest plot of overall subgroup analysis grouped by length of intervention in months

Study	no. of sessions	Std diff in means	Hedge's g	Z-value	p-value
Ostergaard et al., 2014	32	0.000	0.000	0.000	1.000
Loewy et al., 2016	40	-0.077	-0.076	-0.344	0.731
Ventura et al., 2017	66	0.436	0.431	1.901	0.057
Eack et al., 2009	127.5	1.219	1.203	4.255	0.000
Vidarsdottir et al., 2019	36	-0.317	-0.312	-1.103	0.270
Wykes et al., 2007	40	0.361	0.354	1.131	0.258
Piskulic et al., 2015	40	1.137	1.109	2.964	0.003
Wessels et al., 2015	55	-0.004	-0.004	-0.019	0.985
Palma et al., 2019	34	1.639	1.618	5.547	0.000
Penn et al., 2011	36	0.225	0.221	0.743	0.457
Mac Neil et al., 2012	33	0.857	0.840	2.592	0.010
Grano et al., 2016	46	0.670	0.661	2.439	0.015
> 30 sessions		**0.487**	**0.480**	**2.899**	**0.004**
Morrison et al., 2004	9	-0.137	-0.136	-0.955	0.340
Ising et al., 2016	10	0.147	0.147	0.957	0.339
Fowler et al., 2018	16	0.432	0.430	2.554	0.011
Fowler et al., 2009	12	0.139	0.137	0.582	0.561
Bechdolf et al., 2007	23	0.144	0.142	0.582	0.560
Jackson et al., 2007	20	0.382	0.377	1.490	0.136
Addington et al., 2011	12	0.191	0.187	0.562	0.574
Stain et al., 2016	9	-0.174	-0.169	-0.505	0.613
Choi et al., 2016	30	0.024	0.023	0.093	0.926
Lee et al., 2012	20	0.463	0.453	1.372	0.170
Mendella et al., 2015	24	0.045	0.043	0.114	0.909
Ruggeri et al., 2015	27	0.254	0.253	2.443	0.015
Killackey et al., 2008	29.5	1.462	1.433	3.352	0.001
Miklowitz et al., 2014	18	0.475	0.472	2.359	0.018
≤ 30 sessions		**0.225**	**0.223**	**2.989**	**0.003**
Overall		**0.269**	**0.266**	**3.912**	**0.000**

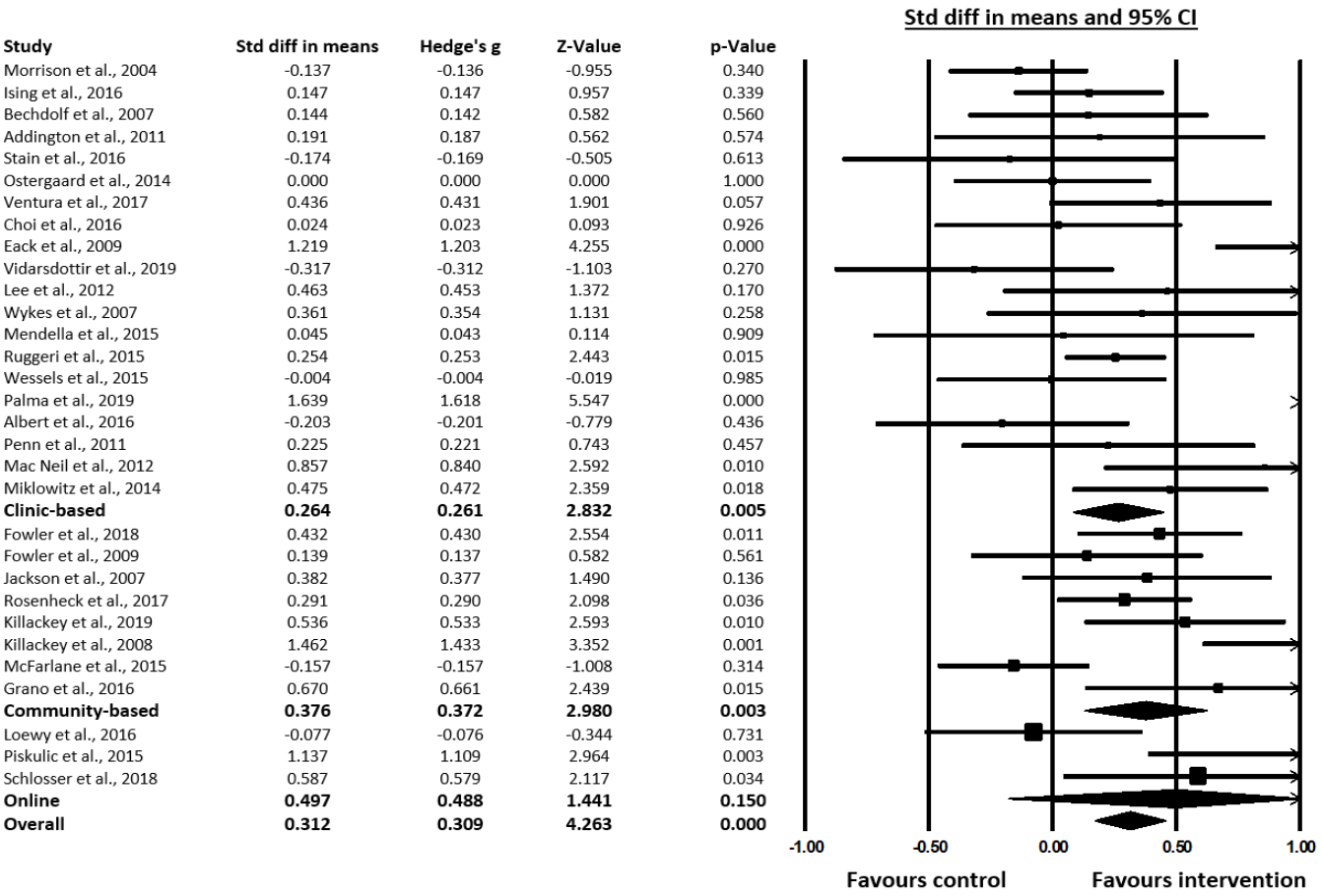


Supplementary Figure S7. Forest plot of overall subgroup analysis grouped by number of sessions

Study	Control condition	Std diff in means	Hedge's g	Z-value	p-value
Morrison et al., 2004	supportive listening	-0.137	-0.136	-0.955	0.340
Fowler et al., 2018	multi-component EIS	0.432	0.430	2.554	0.011
Fowler et al., 2009	case management	0.139	0.137	0.582	0.561
Bechdolf et al., 2007	supportive counselling	0.144	0.142	0.582	0.560
Jackson et al., 2007	befriending	0.382	0.377	1.490	0.136
Addington et al., 2011	supportive therapy	0.191	0.187	0.562	0.574
Stain et al., 2016	non-directive relfective listening	-0.174	-0.169	-0.505	0.613
Ostergaard et al., 2014	multi-component EIS	0.000	0.000	0.000	1.000
Loewy et al., 2016	computer games	-0.077	-0.076	-0.344	0.731
Ventura et al., 2017	multi-component EIS	0.436	0.431	1.901	0.057
Choi et al., 2016	computer games	0.024	0.023	0.093	0.926
Eack et al., 2009	supportive therapy	1.219	1.203	4.255	0.000
Vidarsdottir et al., 2019	multi-component EIS	-0.317	-0.312	-1.103	0.270
Lee et al., 2012	case management	0.463	0.453	1.372	0.170
Piskulic et al., 2015	computer games	1.137	1.109	2.964	0.003
Wessels et al., 2015	supportive counselling	-0.004	-0.004	-0.019	0.985
Albert et al., 2016	multi-component EIS	-0.203	-0.201	-0.779	0.436
Penn et al., 2011	multi-component EIS	0.225	0.221	0.743	0.457
Mac Neil et al., 2012	case management	0.857	0.840	2.592	0.010
Killackey et al., 2019	multi-component EIS	0.536	0.533	2.593	0.010
Killackey et al., 2008	multi-component EIS	1.462	1.433	3.352	0.001
McFarlane et al., 2015	TAU + monitoring	-0.157	-0.157	-1.008	0.314
Miklowitz et al., 2014	psychoeducation	0.475	0.472	2.359	0.018
Active control condition		**0.258**	**0.254**	**3.030**	**0.002**
Ising et al., 2016	TAU	0.147	0.147	0.957	0.339
Wykes et al., 2007	TAU	0.361	0.354	1.131	0.258
Mendella et al., 2015	TAU	0.045	0.043	0.114	0.909
Ruggeri et al., 2015	TAU	0.254	0.253	2.443	0.015
Palma et al., 2019	TAU	1.639	1.618	5.547	0.000
Schlosser et al., 2018	TAU	0.587	0.579	2.117	0.034
Rosenheck et al., 2017	TAU	0.291	0.290	2.098	0.036
Grano et al., 2016	TAU	0.670	0.661	2.439	0.015
Treatment-as-usual condition		**0.464**	**0.458**	**3.373**	**0.001**
Overall		**0.315**	**0.311**	**4.351**	**0.000**

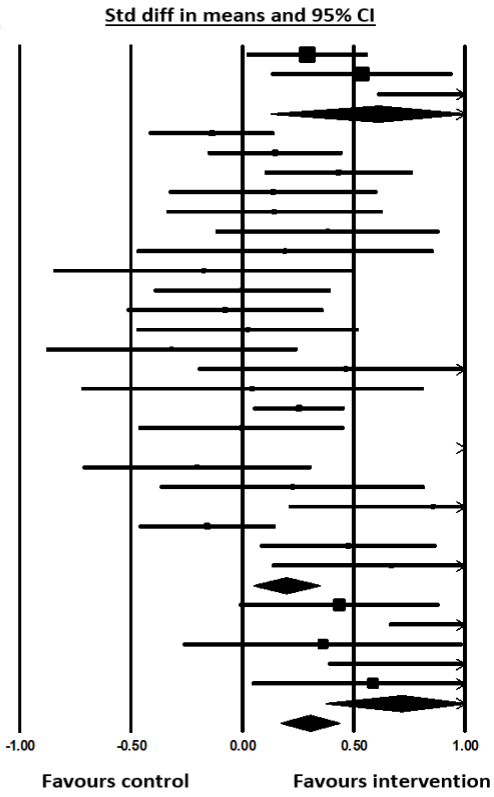


Supplementary Figure S8. Forest plot of overall subgroup analysis grouped by control condition



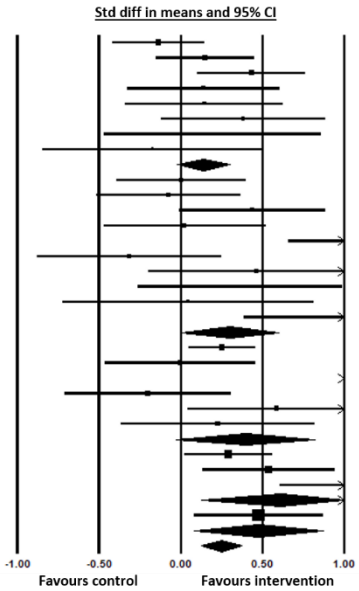
Supplementary Figure S9. Forest plot of overall subgroup analysis grouped by mode of delivery (clinic-based vs community-based vs online)

Study	Outcome measure	Std diff in means	Hedge's g	Z-value	p-value
Rosenheck et al., 2017	employment	0.291	0.290	2.098	0.036
Killackey et al., 2019	employment	0.536	0.533	2.593	0.010
Killackey et al., 2008	employment	1.462	1.433	3.352	0.001
Employment		**0.611**	**0.605**	**2.473**	**0.013**
Morrison et al., 2004	GAF	-0.137	-0.136	-0.955	0.340
Ising et al., 2016	SOFAS	0.147	0.147	0.957	0.339
Fowler et al., 2018	TUS	0.432	0.430	2.554	0.011
Fowler et al., 2009	TUS	0.139	0.137	0.582	0.561
Bechdolf et al., 2007	SAS	0.144	0.142	0.582	0.560
Jackson et al., 2007	SOFAS	0.382	0.377	1.490	0.136
Addington et al., 2011	TUS	0.191	0.187	0.562	0.574
Stain et al., 2016	SOFAS	-0.174	-0.169	-0.505	0.613
Ostergaard et al., 2014	UPSA-B	0.000	0.000	0.000	1.000
Loewy et al., 2016	GAF	-0.077	-0.076	-0.344	0.731
Choi et al., 2016	SAS	0.024	0.023	0.093	0.926
Vidarsdottir et al., 2019	LSP-39	-0.317	-0.312	-1.103	0.270
Lee et al., 2012	SFS	0.463	0.453	1.372	0.170
Mendella et al., 2015	UPSA-B	0.045	0.043	0.114	0.909
Ruggeri et al., 2015	GAF	0.254	0.253	2.443	0.015
Wessels et al., 2015	GAF	-0.004	-0.004	-0.019	0.985
Palma et al., 2019	GAF	1.639	1.618	5.547	0.000
Albert et al., 2016	PSP	-0.203	-0.201	-0.779	0.436
Penn et al., 2011	RFS	0.225	0.221	0.743	0.457
Mac Neil et al., 2012	SOFAS	0.857	0.840	2.592	0.010
McFarlane et al., 2015	GAF	-0.157	-0.157	-1.008	0.314
Miklowitz et al., 2014	GAF	0.475	0.472	2.359	0.018
Grano et al., 2016	GAF	0.670	0.661	2.439	0.015
Global function		**0.197**	**0.195**	**2.602**	**0.009**
Ventura et al., 2017	social attainment	0.436	0.431	1.901	0.057
Eack et al., 2009	social adjustment	1.219	1.203	4.255	0.000
Wykes et al., 2007	SBS	0.361	0.354	1.131	0.258
Piskulic et al., 2015	GFS	1.137	1.109	2.964	0.003
Schlosser et al., 2018	social behaviour	0.587	0.579	2.117	0.034
Social function		**0.716**	**0.705**	**4.080**	**0.000**
Overall		**0.303**	**0.301**	**4.527**	**0.000**



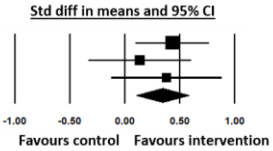
Supplementary Figure S10. Forest plot of overall subgroup analysis grouped by outcome measure (employment vs global function vs social function)

Study name	Sample size	diagnosis	control condition	no. of sessions	outcome type	Std diff in means	Hedge's g	Z-Value	p-Value
Morrison et al., 2004	195	UHR	supportive listening	9	GAF	-0.137	-0.136	-0.955	0.340
Ising et al., 2016	170	UHR	TAU	10	SOFAS	0.147	0.147	0.957	0.339
Fowler et al., 2018	143	early psychosis	multi-component EIS	16	TUS	0.432	0.430	2.554	0.011
Fowler et al., 2009	71	early psychosis	case management	12	TUS	0.139	0.137	0.582	0.561
Bechdolf et al., 2007	67	prodromal psychosis	supportive counselling	23	SAS	0.144	0.142	0.582	0.560
Jackson et al., 2007	62	FEP	befriending	20	SOFAS	0.382	0.377	1.490	0.136
Addington et al., 2011	35	UHR	supportive therapy	12	TUS	0.191	0.187	0.562	0.574
Stain et al., 2016	34	UHR	non-directive relfective listening	9	SOFAS	-0.174	-0.169	-0.505	0.613
Cognitive Behavioural Therapy						**0.139**	**0.138**	**1.699**	**0.089**
Ostergaard et al., 2014	98	FEP	multi-component EIS	32	UPSA-B	<0.001	0.000	<0.001	1.000
Loewy et al., 2016	83	UHR	computer games	40	GAF	-0.077	-0.076	-0.344	0.731
Ventura et al., 2017	78	FEP	multi-component EIS	66	social attainment	0.436	0.431	1.901	0.057
Choi et al., 2016	62	UHR	computer games	30	SAS	0.024	0.023	0.093	0.926
Eack et al., 2009	58	early psychosis	supportive therapy	128	social adjustment	1.219	1.203	4.255	<0.001
Vidarsdottir et al., 2019	49	early psychosis	multi-component EIS	24	LSP-39	-0.317	-0.312	-1.103	0.270
Lee et al., 2012	36	FEP	case management	20	SFS	0.463	0.453	1.372	0.170
Wykes et al., 2007	32	early schizophrenia	TAU	40	SBS	0.361	0.354	1.131	0.258
Mendella et al., 2015	27	FEP	TAU	24	UPSA-B	0.045	0.043	0.114	0.909
Piskulic et al., 2015	25	UHR	computer games	40	GFS	1.137	1.109	2.964	0.003
Cognitive Remediation						**0.301**	**0.296**	**1.984**	**0.047**
Ruggeri et al., 2015	392	FEP	TAU	27	GAF	0.254	0.253	2.443	0.015
Wessels et al., 2015	74	UHR	supportive counselling	55	GAF	-0.004	-0.004	-0.019	0.985
Palma et al., 2019	62	early schizophrenia	TAU	34	GAF	1.639	1.618	5.547	0.000
Albert et al., 2016	59	prodromal schizophrenia	multi-component EIS	NR	PSP	-0.203	-0.201	-0.779	0.436
Schlosser et al., 2018	59	early psychosis	TAU	NR	social behaviour	0.587	0.579	2.117	0.034
Penn et al., 2011	44	FEP	multi-component EIS	36	RFS	0.225	0.221	0.743	0.457
Multi-component Psychosocial Intervention						**0.395**	**0.391**	**1.825**	**0.068**
Rosenheck et al., 2017	227	FEP	TAU	NR	employment	0.291	0.290	2.098	0.036
Killackey et al., 2019	126	FEP	multi-component EIS	NR	employment	0.536	0.533	2.593	0.010
Killackey et al., 2008	41	FEP	multi-component EIS	29.5	employment	1.462	1.433	3.352	0.001
Supported Employment						**0.611**	**0.605**	**2.473**	**0.013**
Miklowitz et al., 2014	102	UHR	psychoeducation	18	GAF	0.475	0.472	2.359	0.018
Family-based Intervention						**0.475**	**0.472**	**2.359**	**0.018**
Overall						**0.251**	**0.248**	**4.005**	**<0.001**



Supplementary Figure S11. Forest plot of summary statistics (SMD – Cohen's d) for intervention groups and overall summary statistics for psychosocial interventions excluding non-RCT studies

Study name	diagnosis	Std diff in means	Hedge's g	Z-Value	p-Value
Fowler et al., 2018	early psychosis	0.432	0.430	2.554	0.011
Fowler et al., 2009	early psychosis	0.139	0.137	0.582	0.561
Jackson et al., 2007	FEP	0.382	0.377	1.490	0.136
Cognitive Behavioural Therapy		**0.345**	**0.341**	**2.836**	**0.005**



Supplementary Figure S12. Forest plot of summary statistics (SMD – Cohen's d) for CBT excluding UHR studies

Appendix D: Published version of study 2

Frawley *et al. Pilot and Feasibility Studies* (2022) 8:109
https://doi.org/10.1186/s40814-022-01064-6

Pilot and Feasibility Studies

STUDY PROTOCOL Open Access

Cognitive Remediation and Social Recovery in Early Psychosis (CReSt-R): protocol for a pilot randomised controlled study

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Abstract

Background: Psychosis, even in its early stages, is associated with significant disability, causing it to be ranked ahead of paraplegia and blindness in those aged 18–35 in terms of years lived with disability. Current pharmacological and psychological interventions have focused primarily on the reduction of positive symptoms (hallucina-tions and delusions), with little benefit to domains of psychosis such as cognitive difficulties and social and occupa-tional functioning.

Methods/design: The CReSt-R intervention trial is a single center, pilot randomised controlled study based at the National University of Ireland (NUI), Galway. The trial will recruit participants from four clinical sites with assessment and intervention completed by the primary NUI Galway team. The trial will explore the feasibility, acceptability, and effectiveness of a novel psychosocial intervention for early psychosis based on a combined cognitive remediation training and cognitive behavioural therapy approach focused on social recovery. Participants, aged 16–35 within the first 5 years of a diagnosed psychotic disorder, will be recruited from the Children and Adolescent Mental Health Service and the Adult Mental Health Services in the region.

Discussion: Cognitive remediation training (for improving cognition) and social recovery focused cognitive behav-ioural therapy, have both separately demonstrated effectiveness. This trial will evaluate the feasibility, acceptability, and explore the efficacy of a treatment approach that combines both approaches as part of an integrated, multicom-ponent intervention.

Trial registration: Cognitive Remediation & Social Recovery in Early Psychosis (CReSt-R): ClincialTrials.gov Identifier NCT04273685. Trial registered Feb 18th, 2020. Last updated April 14th, 2021.

Keywords: Early psychosis, Psychosocial intervention, Social function, Occupational function, Social recovery, Cognitive remediation, Pilot, Feasibility

Background

In psychosis spectrum disorders, there has been a shift in focus from research and development focused purely on pharmacological symptom management to a focus on the broader concept of recovery. Although anti-psychotic medications have been effective in symptom remission, less than half of all schizophrenia patients have been able to achieve recovery [1]. Residual impairments in both

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neurocognition and social cognition, unaddressed by pharmacological intervention, continue to have a significant impact on function and the rate of disability in those living with psychosis [2, 3]. The rate of development of new pharmacological interventions has slowed with no new drug released to the market in approximately 20 years.

While cognitive deficits and their impact on the social and occupational functioning are well established in chronic schizophrenia, their effects in early psychosis (defined as within the first 5 years of a diagnosed psychotic disorder) are less well understood. A meta-analysis recently published by our group explored cognitive predictors of social recovery in early psychosis using cross-sectional and longitudinal data. The meta-analysis comprised 46 studies including 3767 participants and was based on nine cognitive domains. All cognitive domains were related to psychosocial function both cross-sectionally and longitudinally. These associations remained significant even after the effects of symptom severity, duration of untreated psychosis (DUP) and length of illness were accounted for. General cognitive ability (IQ) and social cognition were most strongly associated with both concurrent and long-term function [4].

To understand the relationship between *remission* and recovery in early psychosis, remission has been defined as referring to symptomatic and/or functional improvement over a > 6-month time frame and using specific assessment criteria (The Remission in Schizophrenia Working Group RSWG criteria). *Recovery* on the other hand was defined as symptomatic and functional improvement in social, occupational, and educational domains over a time frame of > 2 years [5]. In their meta-analysis of long-term outcome studies of first episode psychosis (FEP) 58% of participants met remission criteria at a mean of 5 years and 38% met recovery criteria at a mean of 7.2 years.

Key elements of recovery from an individual perspective have been identified as including connectedness, hope, identity, empowerment, and having a meaningful role [6]. However, these concepts are difficult to operationalise and quantify at a service level and so may get 'lost in translation' using conventional outcome measures, such as hospital admission rates, symptom reduction or global level of functioning.

In a systematic review and meta-analysis of 31 studies, we [7] investigated the impact of current psychosocial intervention on social and occupational functioning (both global and individual). We found that cognitive remediation training (CRT) was associated with significant gains in function, similar to chronic schizophrenia. CRT is defined as 'a behavioural training-based intervention that aims to improve cognitive processes [attention, memory, executive function, social cognition, or metacognition] with the goal of durability and generalisability' ('Cognitive Remediation Experts Workshop (CREW)', Florence, April 2010).

Cognitive Behavioural Therapy for psychosis (CBTp) is an evidence-based talking therapy with the primary aim of reducing clinical symptom severity, e.g. hallucinations and reducing relapse rates. This type of therapy was not significantly associated with improved social and occupational functioning. However, CBT focused on social recovery, social recovery therapy (SRT), was associated with significant improvements. Multicomponent interventions were found to be associated with the strongest gains in social and occupational functioning [7]. Across psychosis spectrum disorders, social cognition has been repeatedly linked to functional outcomes [8–11]. Social cognition is reported to mediate the effects of neurocognition on functional outcomes [2, 12–14].

Early intervention in psychosis (EIP) services are multidisciplinary, clinical teams established to seek, identify, and reduce treatment delays at the onset of psychosis. They promote recovery by providing evidence-based intervention thereby reducing the probability of relapse following a first episode of psychosis. The concept, purpose, and effectiveness of *multicomponent intervention* in EIP has been described previously [15]. These interventions included the 'core' components of psychopharmacological treatment (with regular medication review) and family psychoeducation/counselling, alongside 'optional' components of CBT, family therapy, vocational and education counselling, social skills training, crisis management, and a crisis response team. Where does cognition fit in this multicomponent model?

Previously, in a review of social cognitive interventions, it was concluded that in order to impact higher-order social cognitive processes, there needs to be ample opportunity for practice of skills both in a clinical setting as well as in the community [16]. Social cognition is reported to mediate the effects of neurocognition on functional outcomes [2, 12, 14]. This suggests better functional outcomes may be achieved if both neurocognition and social cognition are targeted in intervention and that neurocognitive training alone does not result in significant social cognitive improvements [3, 14].

The CReSt-R study investigates a novel approach to optimising the cognitive and functional benefits of psychological interventions in early psychosis. It involves a multicomponent intervention that combines (a) CRT- a Computerised Interactive Remediation of Cognition-Training for Schizophrenia (CIRCuiTS) [17–19] with (b) social recovery therapy (SRT) [20–22]. In so doing, the aim is to target both social and occupational functioning

and social cognition in young people living with psychosis, two outcomes of interest for this study.

CRT is recognised as an effective treatment in schizophrenia generally with a large meta-analysis reporting an effect size of Cohen's $d = 0.45$ for cognitive performance, $d = 0.42$ for psychosocial functioning and $d = 0.18$ for symptom severity [23]. CRT programmes have evolved over the years with a variety of programme protocols and specific techniques now reported in the literature. An expert working group, identified four core features of CRT, including facilitation by a therapist, cognitive exercise, procedures to develop problem-solving strategies, and procedures to facilitate transfer to real-world functioning [24]. A meta-analysis supports this emphasis, finding that better outcomes following CRT were associated with an active and trained therapist, structured development of cognitive strategies, and integration with psychosocial rehabilitation [25]. The CIRCuiTS programme, outlined in the "Methods/design" section below, embodies these core elements. It is also informed by a metacognitive model, emphasising self-awareness, self-monitoring, and self-direction when completing the programme tasks and the transfer of these skills to everyday life.

SRT is informed by cognitive behavioural theory. It is an evolved form of cognitive behavioural therapy (CBT) with an emphasis on assertive outreach and behavioural experimentation. Similar to the CIRCuiTS programme it aims to apply cognitive work and newly acquired knowledge and strategies to everyday life with a focus on self-awareness and self-monitoring.

The CReSt-R study will contribute to the cognitive remediation field and the wider field of recovery in early psychosis by exploring the feasibility, acceptability, and effectiveness of this multicomponent psychosocial intervention with the hypothesis of a greater impact on social and occupational functioning and social cognition compared to treatment as usual in the target group. Whilst both intervention components have demonstrated efficacy in previous studies in addition to being found acceptable to participants [17–22], the acceptability of the combined, multicomponent intervention to young people aged 16–35 in the early psychosis population is unknown. In addition, the feasibility of delivering the multicomponent intervention and running a larger scale randomised control trial in Ireland is unknown.

Methods/design

Aims and objectives of the CReSt-R pilot randomised controlled study

The aim of the CReSt-R pilot randomised control study is to gather and analyse acceptability and feasibility data to (1) further develop and refine the novel, multicomponent CReSt-R intervention (2) investigate the feasibility of delivering and evaluating the intervention in future definitive trials. Specifically, the study objectives (outlined in further detail in "The CreSt-R intervention and control condition", "Feasibility", "Acceptability", "Estimating treatment effect sizes" sections) include the following:

(1) To collect qualitative and quantitative data to assess the feasibility of the intervention with indicators in the areas of process, intervention, and resources.
(2) To investigate if the CReSt-R intervention is acceptable to young people, aged 16–35, who are within the first 5 years of a diagnosed psychotic disorder.
(3) To explore the effectiveness of the intervention by analyzing primary and secondary outcome data to provide treatment effect estimates, thus informing future trial design.

Ethics, consent, and permissions

This study was approved by the Galway Clinical Research Ethics Committee, Merlin Park Hospital, Galway, Ireland. All participants will provide informed signed consent. The ethics application also detailed general data protection regulation (GDPR) considerations, the proposed management of vulnerable individuals in the study and assent for participants aged under 18 years of age.

Setting and participants

This is a community-based study and will recruit participants from the Children and Adolescent Mental Health Service (CAMHS) and the Adult Mental Health Service (AMHS). Recruitment referrals from primary care providers and self-referrals are also accepted on a case-by-case basis with a primary clinical contact deemed essential for participation. Collaboration with clinical teams is anticipated to assist with recruiting adequate number of participants for this study. A sample size of 30 is a common 'rule of thumb' in pilot studies [26, 27], with 15 in the intervention arm and 15 in the control arm considered adequate in generating data to explore the feasibility and acceptability of the proposed intervention and in providing an estimate of the intervention's efficacy for planning a definitive intervention trial. This pragmatic approach is consistent with other feasibility studies in the area of early psychosis [28] and in line with current recommendations for pilot studies [29].

Inclusion criteria for the study are being aged between 16 and 35 years of age, within the first 5 years of a diagnosed psychotic illness (based on time since first contact with a clinical service), community based, clinically stable and having the ability to give consent. Exclusion criteria are having a history of organic impairment (including

IQ < 70), history of a head injury with loss of consciousness > 5-min duration and drug abuse in the preceding month. Confirmation of diagnosis, timeframe of onset of psychotic symptoms, presence of cognitive and social and occupational difficulties will be provided via a referral form completed by the primary clinical contact. Participants may withdraw from the study at any time.

Study design, randomisation, and treatment allocation

A randomised pilot study with a controlled, outcome-assessor-blind, parallel- group design will be implemented. Randomisation will use a permuted block design, using a computerised random number generator with predetermined 1:1 allocation ratio and will be completed by an independent statistician. The study research assistant will provide an information sheet to a potential participant and answer any questions they may have before obtaining written consent. There will be a 7-day cooling off period between provision of consent and enrolment to the study. Upon enrolment into the study the participants will be randomised to the intervention group (CReSt-R) or the control group. Both interventions are detailed below. After randomisation, the participant will complete baseline assessments with an assessor blind to treatment allocation. All participants will be instructed not to reveal their treatment allocation prior to each follow-up assessment. Should the blind be broken for any participant, this will be noted and reported to the principal investigator. The primary clinical contact for each individual participant will be informed of treatment allocation. The consort diagram for study procedure is contained in Fig. 1.

The CreSt-R intervention and control condition

Component 1

The CRT programme used in this study is the Computerised Interactive Remediation of Cognition-Training for Schizophrenia (CIRCuiTS). CIRCuiTS is a web-based CRT programme which targets metacognition, specifically strategy use, in addition to massed practice of cognitive functions (attention, memory, and executive functioning). Collaborative goal setting related to real-world tasks are integral to the programme with the programme tasks and exercises increasing in difficulty in response to the participant's performance and progress. The protocol for CIRCuiTS training will follow that of a previous efficacy study [19]. This will be the primary focus of 1:1 therapy for the first weeks with remote practice sessions occurring between therapy visits. After 4 weeks, remote practice will continue and the focus of in-person therapy sessions will bridge to Social Recovery Therapy as detailed below.

Component 2

Social recovery therapy (SRT) focuses on addressing barriers to individuals interacting in their social environment, e.g. social anxiety. It is informed by cognitive behavioural theory and addresses individual goals. SRT follows an established protocol [20, 21]. In summary, this consists of therapy delivered in three stages. Stage 1 will include engagement and formulation with the purpose of identifying a problem list and establishing a therapeutic relationship. Stage 2 will include preparing for new activities with identification of pathways to activity and collaboration with community stakeholders. Stage 3 will include engagement in new activities using behavioural experiments to promote social activity. This is the primary focus of in-person therapy sessions from week 5 to 10 alongside remote practice of the CRT programme. There is emerging evidence to support brief intervention in both CRT [30] and CBTp [31]. Rationale for intervention duration in the CReSt-R study builds upon this recent work in addition to a previous study by our group which reported significant gains in both neuropsychological function and social function at follow-up post an 8-week, low support, remotely accessible CRT programme for chronic psychosis [32]. Intervention duration will also be considered as a feasibility indicator in this study.

In the control group of the study participants will receive treatment as usual (TAU) plus 10 weeks of 1:1 non-directive counselling matching the intervention group for time. This consists of 10 1:1, hour-long sessions with the same intervention therapist who delivers the CRT intervention. The therapy in the control condition is characterised by empathy, unconditional positive regard, congruence, and non-directivity. Notes pertaining to each session are recorded and clinical supervision is provided by the principal investigator.

The CReSt-R intervention was initially intended for delivery in in-person sessions with a strong emphasis on assertive outreach, community-embedded intervention delivery, and therapeutic rapport. However, in response to the COVID-19 pandemic and resulting public health guidelines, the protocol was revised to enable adaptation to these circumstances. The outcome measures and delivery of the intervention can now be offered face to face, entirely online, or in a blended approach remaining true to the core therapeutic principles of both components of the multicomponent intervention. These changes reflect broader change in clinical practice in response to the global pandemic and identified opportunities in this area of intervention delivery [33]. The delivery mode of the intervention will be considered in the analysis and interpretation of results.

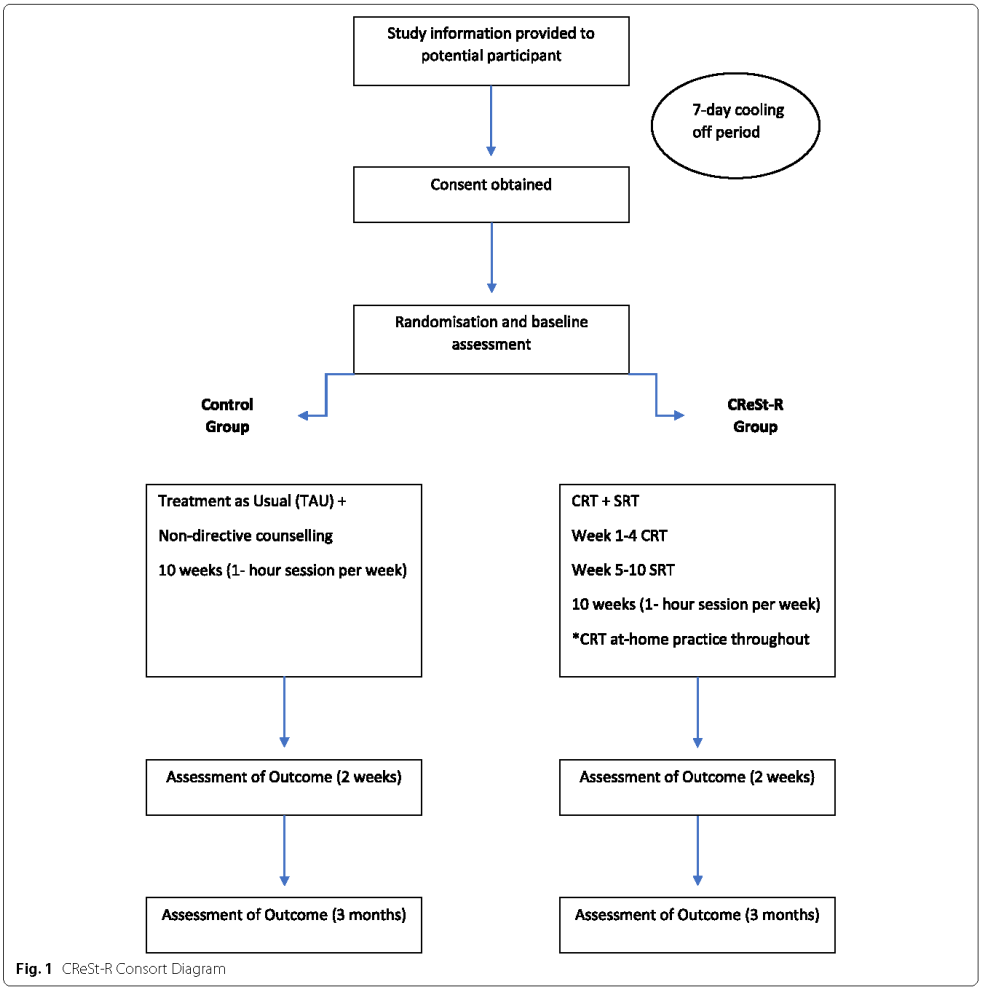

Fig. 1 CReSt-R Consort Diagram

Feasibility

All statistical analyses will occur after completion of data collection and will adopt the intention-to-treat (ITT) principle. All data will be processed in SPSS version 27. The first objective of the analysis, assessing feasibility, will consist of descriptive statistics with derivation of means and standard deviations or medians, minimum/maximum values and interquartile range for continuous measures and proportions for ordinal or multinomial categorical and binary coded measures as appropriate. Participants' baseline demographics and clinical characteristics will also be reported. Missing data patterns will be described for all three outcome time points.

Process feasibility indicators include recruitment and retention rates reported per month of trial and in total at trial completion, appropriateness of inclusion criteria and reasons for exclusion from the trial as reported by clinical collaborators, effectiveness of randomisation procedure, and effectiveness of blinding procedures.

Intervention feasibility indicators include participant adherence to the trial protocol, intervention duration/therapy dosage and therapy fidelity.

Resource feasibility indicators include therapist time in session, remote support, and clinical supervision; intervention costs for software, running costs, and participant reimbursement for assessment sessions. See Table 1 for further detail of assessment of feasibility indicators.

Criteria for progression to a larger study will be assessed using three key feasibility indicators namely (1) recruitment rate (2) retention rate and (3) acceptability of the intervention. A system of proceed, amend, or stop will be utilised modeled on previously used traffic light systems [35] (see Table 2). This system operates on the use of guidelines rather than strict thresholds in line with current recommendations [35, 37–39]. A decision to progress the trial will be decided by the above criteria, as well as discussion with the study research team, clinical collaborators, and patient–public involvement panel.

Acceptability

Acceptability of the intervention will be assessed using the Intrinsic Motivation Inventory (IMI) administered on completion of the study [34]. A qualitative semi-structured interview schedule has also been developed for completion at the end of the intervention (see Appendix 1). This embedded qualitative study will allow participants to provide feedback focusing on the following: their general experience of participating in the intervention, intervention components, experience of recruitment, communication, and perceived benefits and challenges of participating in the intervention. The qualitative data will be analysed using a reflexive thematic analysis approach [40]. The acceptability aspect of this study will be integral in further developing the multicomponent intervention and optimising clinical utility. The interview schedule itself will be reviewed for adaptation for future use based on interviewer and interviewee feedback.

Estimating treatment effect sizes

To clarify, this study does not aim to determine treatment effect. However, to inform statistical power calculations for primary and secondary treatment outcomes in advance of a full RCT, estimates of treatment effect sizes will be obtained using linear mixed models. These analyses, completed in SPSS version 27, will provide a treatment effect estimate on each outcome measure at 2 and

Table 1 Feasibility indicators assessment

Feasibility indicator	Assessment
[a]Recruitment rate	% of participants recruited/time
[b]Retention rate	% of participants who complete T1, T2, and T3 outcome assessments Descriptive data on participants who leave the study early-therapy group (intervention v's control), # of sessions completed, cited reason for leaving.
Inclusion criteria	Completion rate of referral form by clinical contact Descriptive data on reasons for exclusion from study % of participants referred to study who meet inclusion criteria
Randomisation procedure	Evaluation of 1:1 ratio at end of trial (# of intervention participants: # control participants) Logged data on any errors made
Blinding procedure	Blinding in this trial will be assessed by asking blinded assessors to guess the trial group assignment and comparing these responses to what would be expected by chance Logged data on unblinding occurrences during trial
Adherence/intervention duration/therapy dosage	# of therapy sessions completed per participant Time spent on CIRCuiTS (at-home work) per participant. (logged on CIRCuiTS software platform) Time spent on at-home behavioural experiments (logged per participant throughout trial)
Therapy fidelity	Completion rate of clinical supervision sessions Completion rate of fidelity checklists
Therapist time- in session	Total time spent by therapist in session and documentation per month (data logged throughout study)
Therapist time- remote support	Total time spent communicating via email, text, or phone outside of therapy session per month (data logged throughout study)
Clinical supervision	# of clinical supervision sessions per month
Software	Total cost of CIRCuiTs license software per month
Running costs	Total cost of study expenses per month, e.g. study phone
Participant reimbursement	Total cost of participant reimbursement for assessment sessions per month
[c]Qualitative study	Reflexive thematic analysis of semi-structured interview data
Intrinsic Motivation Inventory [34]	Completion rate and results of IMI

[a, b, c] Key feasibility indicators for progression

Table 2 Progression criteria

Key indicator	Proceed	Amend	Stop
Recruitment rate *Target figure:* 30 participants	≥ 70% of target number	51–69 % of target number	≤ 50% of target number
Retention rate *Target figure:* 75% of participants randomised to intervention group will complete outcome measures at T1, T2, and T3 [36]	≥ 70% of target number	51–69% of target number	≤ 50% of target number
Acceptability	Intervention is described as acceptable by participants in its current form	Intervention is described as acceptable with recommended changes to improve participant experience	Intervention is described as unacceptable by participants
Action	Continue with intervention and study design with collaboration between research team, clinical collaborators, and PPI contributors	Consultation with research team, clinical collaborators, and PPI contributors regarding necessary amendments to the intervention and study design	No progression to further trial

12 weeks post-intervention. Outcome measures at these two time points will be entered into the model as the dependent variables with fixed effects of study arm, baseline outcome measures, time, and a time point by study arm interaction. Inclusion of baseline outcome measures accounts for their potential prediction of future outcome and will contribute towards accurate effect estimates. A random effect for participant will also be entered into the model to account for correlations between the two time points (repeated measures) per participant. This analysis will be carried out by the trial statistician.

Assessment battery

Primary outcome measure

Social and occupational functioning will be assessed using the Social and Occupational Functional Assessment Scale (SOFAS) [41] with an additional secondary outcome included below.

Secondary outcome measures

1. A secondary *social and occupational functioning* measure will be the Time Use Survey [42].
2. *Social cognition* will be measured using a battery of assessments based on the recommendations from the Social Cognition Psychometric Evaluation Study (SCOPE) final Validation Study [11]. These will include (a) The Emotion Recognition Task (ERT) from the Cambridge Neuropsychological Test Automated Battery (Cambridge Cognition Ltd.), (b) the Hinting Task [43], (c) The Bell Lysaker Emotion Recognition Task (BLERT) [44], and (d) the Reading the Mind in the Eyes Task [45] as operationalised in our previous CRT trial [32].
3. *Cognitive function* will be assessed in terms of general cognitive ability, memory function and executive function. General cognitive ability will be measured using the similarities and matrix reasoning subtests from the Wechsler abbreviated scale of intelligence [46]. Memory function will be assessed using the logical memory subtest and the letter number sequencing task from the Wechsler Memory scale 3rd edition [47]. Visual memory will be measured using the Rey Osterreith Complex Figure (ROCF) [48]. Executive functioning will be measured by the STROOP [49].
4. The Intrinsic Motivation Inventory for Schizophrenia Research [34] will assess intrinsic motivation and self-regulation. Subscales of the assessment will include interest/enjoyment, perceived competence, effort, value/usefulness, felt pressure and tension, and perceived choice while participating in the study.
5. The Need for Cognition Scale (NCS) [50] will assess the degree to which participants seek out cognitively challenging activities of daily living and will provide supplementary information to the social and occupational functioning outcome measures.
6. *Clinical Assessment* will include the Positive and Negative Syndrome Scale (PANSS) [51] (see Table 3).

Discussion

A strength of the protocol is the novelty of the combined intervention and in particular in the early psychosis cohort. The robust outcome assessment battery will enable us to estimate efficacy parameters for the intervention so as to inform further definitive trials in terms of social and occupational functioning, social cognition, general cognition, and other self-report measures. Data on feasibility key indicators of intervention delivery will also assist us in exploring the potential use of the intervention in clinical practice. Potential limitations of the study include the challenge of recruitment of participants

Table 3 CReSt-R outcome measures

Primary outcome measure	Social and Occupational Functioning: Social and Occupational Functional Assessment Scale (SOFAS) [41]
Secondary outcome measures	Function: The Time Use Survey [42] Social Cognition: CANTAB Emotion Recognition Task (ERT) The Reading the Mind in the Eyes Test [45] The Hinting Task [43] The Bell Lysaker Emotion Recognition Task (BLERT) [44] General Cognition: Wechsler Adult Scale of Intelligence 3rd edition (WAIS-III)-The similarities and matrix reasoning subtests [46] Wechsler Memory scale 3rd edition- logical memory subtest [47] Rey Osterreith Complex Figure (ROCF) [48] The Stroop Test [49] Clinical Measures: Positive and Negative Syndrome Scale (PANSS) [51] Self-report measures: The Need for Cognition Scale (NCS) [50] Intrinsic Motivation Inventory (IMI) [34]

in this difficult to ascertain cohort. It is also noted the varying modes of delivery of the intervention (online, blended, in-person), whilst potentially acceptable to participants, need to be considered as part of the interpretation of data collected in the study and the potential both to inform a definitive trial and/or translate the intervention into clinical practice settings.

Trial status

This trial is ongoing. Trial Registration: ClinicalTrials.gov Identifier: NCT04273685. First received: February 18th 2020

Abbreviations

AMHS: Adult Mental Health Service; BLERT: The Bell Lysaker Emotion Recognition Task; CAMHS: Children and Adolescent Mental Health Service; CBT: Cognitive behavioural therapy; CBTp: Cognitive behavioural therapy for psychosis; CIRCuiTS: Computerised Interactive Remediation of Cognition-Training for Schizophrenia; CReSt-R: Cognitive Remediation and Social Recovery in Early Psychosis Study; CREW: Cognitive Remediation Experts Workshop; CRT: Cognitive remediation training; DUP: Duration of untreated psychosis; EIP: Early intervention in psychosis; ERT: Emotion recognition task; FEP: First episode psychosis; GDPR: General data protection regulation; IMI: Intrinsic Motivation Inventory; ITT: Intention to treat; IQ: Intelligence quotient; NCS: Need for cognition scale; NUI: National University of Ireland; PANSS: Positive and Negative Symptom Scale; ROCF: Rey Osterrith complex figure; RSWG: Remission in schizophrenia working group; SCOPE: Social cognition psychometric evaluation study; SMD: Standardised mean difference; SOFAS: Social and occupational functioning scale; SRT: Social recovery therapy; TAU: Treatment as usual.

Acknowledgements

The authors would like to acknowledge the contribution of all public and patient involvement contributors to the study to date including patients, clinicians, and the Youlead Youth Advisory Panel (YAP). We are grateful to the CIRCuiTS and SRT program developers and to the funders of this study.

Authors' contributions

EF and GD originated the conception and design of the study. EF leads the trial and will complete the analysis and interpretation of data with substantial involvement from GD also. MC, DC, ER, BH, CB, CM, DF, and TW all met guidelines for authorship. All authors reviewed and approved the manuscript.

Funding

This work was funded by the Irish Health Research Board as part of the collaborative doctoral award in Youth Mental Health [YOULEAD] (HRB grant number: CDA-2018-001).

Availability of data and materials

The full protocol in addition to datasets and statistical code generated during the current study will be available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was approved by the Galway Clinical Research Ethics Committee, Merlin Park Hospital, Galway, Ireland (reference number C.A. 2182).

Consent for publication

Not applicable.

Competing interests

Author TW was involved with development of the CIRCuiTS program however is not involved with supervising any of the assessment procedures or data analysis. Similarly, author DF was involved in developing social recovery therapy however is also not involved in assessment procedures or data analysis.

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Received: 7 December 2021 Accepted: 6 May 2022
Published online: 24 May 2022

References

1. Green MF. Impact of Cognitive and Social Cognitive Impairment on Functional Outcomes in Patients with Schizophrenia. J Clin Psychiatry. 2016;77(Suppl 2):8–11.

2. Fett A, Viechtbauer W, Dominguez M, Penn D, Van Os J, Krabbendam L. The relationship between neurocognition and social cognition with functional outcomes in schizophrenia: a meta-analysis. Neurosci. Biobehav. Rev. 2011;35(3):573–88.
3. Horan W, Green M. Treatment of social cognition in schizophrenia: Current status and future directions. Schizophr. Res. 2019;203:3–11.
4. Cowman M, Holleran L, Lonergan E, O'Connor K, Birchwood M, Donohoe G. Cognitive predictors of social and occupational functioning in early psychosis: a systematic review and meta-analysis of cross-sectional and longitudinal data. Schizophr. Bull. 2021;47(5):1243–53.
5. Lally J, Ajnakina O, Stubbs B, Cullinane M, Murphy KC, Gaughran F, et al. Remission and recovery from first-episode psychosis in adults: systematic review and meta-analysis of long-term outcome studies. The Br J Psychiatry : the journal of mental science. 2017;211 Suppl 6:350–8.
6. Slade M, Bird V, Le Boutillier C, Williams J, McCrone P, Leamy M. REFOCUS Trial: protocol for a cluster randomised controlled trial of a pro-recovery intervention within community based mental health teams. BMC Psychiatry. 2011;11:185.
7. Frawley E, Cowman M, Lepage M, Donohoe G. Social and occupational recovery in early psychosis: a systematic review and meta-analysis of psychosocial interventions. Psychol. Med. 2021;3:1–12.
8. Bora E, Yucel M, Pantelis C. Theory of mind impairment in schizophrenia: metaanalysis. Schizophr. Res. 2009;109:1–9.
9. Horan W, Kern R, Shokat-Fadai K, Sergi M, Wynn J, Green M. Social cognitive skills training in schizophrenia: an initial efficacy study of stabilized outpatients. Schizophr. Res. 2009;107(1):47–54.
10. Kurtz M, Richardson C. Social cognitive training for schizophrenia: a metaanalytic investigation of controlled research. Schizophr. Bull. 2012;38(5):1092–104.
11. Pinkham A, Penn D, Green M, Buck B, Healey K, Harvey P. The social cognition psychometric evaluation study: results of the expert survey and RAND panel. Schizophr. Bull. 2013;40(4):813–23.
12. Addington J, Saeedi H, Addington D. Facial affect recognition: a mediator between cognitive and social functioning in psychosis? Schizophr. Res. 2006;85(1-3):142–50.
13. McGlade N, Behan C, Hayden J, O'Donoghue T, Peel R, Haq F, et al. Mental state decoding v. mental state reasoning as a mediator between cognitive and social function in psychosis. Br J Psychiatry. 2008;193(1):77–8.
14. Green M, Horan W. Social cognition in schizophrenia. Current Directions. Psych. Sci. 2010;19(4):243–8.
15. Correll CU, Galling B, Pawar A, Krivko A, Bonetto C, Ruggeri M, et al. Comparison of early intervention services vs treatment as usual for early-phase psychosis: a systematic review, meta-analysis, and meta-regression. JAMA Psychiatry. 2018;75(6):555–65.
16. Fiszdon JM, Reddy LF. Review of social cognitive treatment for psychosis. Clin.Psychol. Rev. 2012;32:724–40.
17. Reeder C, Wykes T. Cognitive Interaction Remediation of Cognition - a Training for Schizophrenia (CIRCuiTS). UK: King's College London; 2010.
18. Reeder C, Huddy V, Cella M, Taylor R, Greenwood K, Landau S, et al. A new generation computerised metacognitive cognitive remediation programme for schizophrenia (CIRCuiTS): a randomised controlled trial. Psych. Med. 2017;47(15):2720–30.
19. Reeder C, Pile V, Crawford P, Cella M, Rose D, Wykes T, et al. The Feasibility and Acceptability to Service Users of CIRCuiTS, a computerized cognitive remediation therapy programme for schizophrenia. Behav Cogn Psychother. 2016;44(3):288–305.
20. Fowler D, Hodgekins J, Painter M, et al. Cognitive behaviour therapy for improving social recovery in psychosis: a report from the ISREP MRC Trial Platform Study (Improving Social Recovery in Early Psychosis). Psychol Med. 2009;39:1627–36.
21. Fowler D, French P, Hodgekins J, et al. CBT to address and prevent social disability in early and emerging psychosis. In: Steel C, editor. CBT for schizophrenia: evidence-based interventions and future directions. Oxford: Wiley; 2013. p. 143–67.
22. Gee B, Notley C, Byrne R, Clarke T, Hodgekins J, French P, et al. Young people's experiences of social recovery cognitive behavioural therapy and treatment as usual in the PRODIGY trial. Early Intervention Psychiatry. 2016;12(5):879–85.
23. Wykes T, Huddy V, Cellard C, Mcgurk SR, Czobor P. A meta-analysis of cognitive remediation for schizophrenia: methodology and effect sizes. Am. J. Psychiatry. 2011;168(5):472–85.
24. Bowie CR, Bell MD, Fiszdon JM, Johannesen JK, Lindenmayer JP, McGurk SR, et al. Cognitive remediation for schizophrenia: an expert working group white paper on core techniques. Schizophr. Res. 2020;215:49–53.
25. Vita A, Barlati S, Ceraso A, et al. Effectiveness, core elements, and moderators of response of cognitive remediation for schizophrenia: a systematic review and meta-analysis of randomized clinical trials. JAMA Psychiatry. 2021;78(8):848–58.
26. Browne RH. On the use of a pilot sample for sample size determination. Stat Med. 1995;14:1933–40.
27. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. J Eval in Clin Pract. 2004;10:307–12.
28. Zisman-Ilani Y, Hurford I, Bowen A, et al. Evaluating the feasibility of a decision aid to promote shared decision making among young adults with first-episode psychosis: protocol for a pilot study. Pilot Feasibility Stud. 2021; https://doi.org/10.1186/s40814-020-00757-0.
29. Leon A, Davis L, Kraemer H. The role and interpretation of pilot studies in clinical research. J Psychiatr Res. 2011;45(5):626–9.
30. Tsapekos D, Taylor R, Cella M. Feasibility and acceptability of brief cognitive remediation targeting metacognition in acute inpatients with psychosis: a case series. Neuropsychol Rehabil. 2017;29:361–75.
31. Turkington D, Munetz M, Pelton J, Montesano V, Sivec H, Nausheen B, et al. High yield cognitive behavioural techniques for psychosis delivered by case managers to their clients with persistent psychotic symptoms: an exploratory trial. J Nerv Mental Dis. 2014;1:30–4.
32. Donohoe G, Dillon R, Hargreaves A, Mothersill O, Castorina M, Furey E, et al. Effectiveness of a low support, remotely accessible, cognitive remediation training programme for chronic psychosis: cognitive, functional and cortical outcomes from a single blind randomised controlled trial. Psychol Med. 2018;48(5):751–764.
33. Torous J, Wykes T. Opportunities from the coronavirus disease 2019 pandemic for transforming psychiatric care with telehealth. JAMA Psychiatry. 2020;77(12):1205–6.
34. Choi J, Mogami T, Medalia A. Intrinsic motivation inventory: an adapted measure for schizophrenia research. Schizophr. Bull. 2010;36(5):966–76.
35. Avery K, Williamson P, Gamble C, O'Connell Francischetto E, Metcalfe C, Davidson P, et al. Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies. BMJ Open. 2017. https://doi.org/10.1136/bmjopen-2016-013537.
36. Szymczynska P, Walsh S, Greenberg L, Priebe S. Attrition in trials evaluating complex interventions for schizophrenia: systematic review and meta-analysis. J Psychiatr Res. 2017;90:67–77.
37. Eldridge S, Chan C, Campbell M, Bond C, Hopewell S, Thabane L et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. Pilot Feasib Stud 2016; doi:https://doi.org/10.1136/bmj.i5239
38. Mbuagbaw L, Kosa S, Lawson D, Stalteri R, Olaiya O, Alotaibi A, et al. The reporting of progression criteria in protocols of pilot trials designed to assess the feasibility of main trials is insufficient: a meta-epidemiological study. Pilot Feasib Stud. 2019. https://doi.org/10.1186/s40814-019-0500-z.
39. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios L, et al. A tutorial on pilot studies: the what, why and how. BMC Med Res Methodol. 2010. https://doi.org/10.1186/1471-2288-10-1.
40. Braun V, Clarke V. Using thematic analysis in psychology. Qual. Res. Psychol. 2006;3(2):77–101.
41. Rybarczk B. Social and Occupational functioning assessment scale (SOFAS). In: Kreutzer J, DeLuca J, Caplan B, editors. Encyclopaedia of Clinical Neuropsychology. New York: Springer; 2011. p. 2313.
42. Hodgekins J, French P, Birchwood M, Mugford M, Christopher R, Marshall M, et al. Comparing time use in individuals at different stages of psychosis and a non-clinical comparison group. Schizophrenia Res. 2015;161(2-3):188–93.
43. Corcoran R, Mercer G, Frith CD. Schizophrenia, symptomatology and social inference: Investigating "theory of mind" in people with schizophrenia. Schizophr Res. 1995;17:5–13.
44. Bryson G, Bell M, Lysaker P. Affect recognition in schizophrenia: a function of global impairment or a specifc cognitive defcit. Psychiatry Res. 1997;71:105–13.
45. Baron-Cohen S, Wheelwright S, Hill J, Raste Y, Plumb I. The "Reading the Mind in the Eyes" Test revised version: a study with normal adults, and adults with Asperger syndrome or high-functioning autism. J Child Psychol Psychiatry. 2001;42:241–51.

46. Wechsler D. Wechsler Adult Intelligence Scale 3rd Ed. (WAIS-III). N.Y.: Psychological Corporation; 1997.
47. Wechsler D. Wechsler Memory Scale, 3rd edn. (WMS- III). New York: The Psychological Corporation; 1998.
48. Osterrieth PA. Le Test du copie d'une figure complexe/ Test of coping a complex figure; Contribution to the study of perception and memory. Arch Psychol. 1944;30:206–356.
49. Stroop JR. Studies of interference in serial verbal reactions. J Exp Psychol. 1935;18:643–62.
50. Cacioppo J, Petty R, Feng KC. The efficient assessment of need for cognition. J Pers Assess. 1984;48(3):306–7.
51. Kay SR, Fiszbein A, Opler LA. The positive and negative syndrome scale (PANSS) for schizophrenia. Schizophr. Bull. 1987;13(2):261–76.

Publisher's Note

Appendix E: Ethics Approval from Galway Research Ethics Committee

Saolta
Grúpa Ollscoile Cúram Sláinte
University Health Care Group

Ospidéal na h-Ollscoile, Páirc Mheirlinne
Merlin Park University Hospital
GALWAY UNIVERSITY HOSPITALS

Clinical Research Ethics Committee
Room 59
1st Floor
HR Building
Merlin Park Hospital
Galway.

24th May, 2019.

Professor Gary Donohoe
School of Psychology
National University of Ireland
University Road
Galway.

Ref: C.A. 2182 - ***Cognitive Remediation & Social Recovery in Early Psychosis (CReSt-R)***

Dear Professor Donohoe,

I have considered and reviewed the above submission, and I wish to confirm that I am happy to grant Chairman's approval to proceed.

'This submission has been reviewed from an ethical perspective only. It is the responsibility of the PI/sponsor/data controller and relevant Data Protection Officer to ensure and monitor compliance with any relevant legislation in the country where the study is due to take place or any local policy in the site where the study is due to take place.'

Yours sincerely,

B. Gerard Loftus FRCPI,MD
Emeritus Professor of Paediatrics, NUI,Galway
Adjunct Professor of Paediatrics, IMU, Kuala Lumpur
Chair, Galway Clinical Research Ethics Committee.

c.c. Professor Colm McDonald, Department of Psychiatry, *Clinical Science Institute* National University of Ireland, Galway.

Dr. Brian Hallahan, Senior Lecturer, Department of Psychiatry, *Clinical Science* Institute, National University of Ireland, Galway.

Ms. Emma Frawley, Senior Occupational Therapist, Clinical Research Fellow, School of Psychology, NUI, Galway.

Appendix F: CReSt-R Public Recruitment Poster

Study of new therapy to improve everyday function

A new therapy study focusing on young people living with psychosis is being run by Prof. Gary Donohoe and Emma Frawley, School of Psychology, NUI Galway

To participate:

Are you aged between 16 and 30?

Have you experienced psychosis?

Do you have everyday challenges with thinking?

Do you find social activities challenging?

To learn more and to see if the CReSt-R study is right for you, contact:

CRESTR@nuigalway.ie • 086 852 7199

CRESt-R YOULEAD HRB Health Research Board NUI Galway OÉ Gaillimh

Appendix G: CReSt-R Clinical Recruitment Poster

Cognitive Remediation and Social Recovery in Early Psychosis Study

Is your patient:

- ✓ Aged between 18 and 35 years' old?

Inclusion Criteria:

- ✓ History of psychosis: within the first five years of a diagnosed psychotic illness (based on time since first contact with services for a psychotic episode)
- ✓ Community-based and clinically stable (in opinion of primary treating team)

Exclusion Criteria:

- ✓ History of organic Impairment
- ✓ History of head injury with loss of consciousness > 5-minute duration
- ✓ Drug abuse in the preceding month

Contact:

Emma Frawley Emma.frawley@nuigalway.ie 086 852 7199

Prof. Gary Donohoe gary.donohoe@nuigalway.ie

Appendix H: Participant Information Sheet

Letter of Information to Participants

Project Title: Cognitive Remediation & Social Recovery in Early Psychosis (CReSt-R)

About this information leaflet:

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. This Participant Information Sheet will tell you about the purpose of the research, along with its potential risks and benefits.

There will be a screening process to ensure that you are eligible and that it is safe for you to take part in the study. If eligible, and you agree to take part, we will ask you to sign a consent form. Only the minimum amount of data necessary for the study is being sought. If there is anything that you are not clear about, we will be happy to explain it to you. Please take as much time as you need to read it. You will also be given a copy of this participant information sheet and the consent form to keep. You should only consent to participate in this research study when you feel that you understand what is being asked of you, and you have had enough time to think about your decision.

Description of the study:

This study is researching social cognition and social and occupational functioning in young people aged 16 to 35 living with psychosis. What does that mean?

The word **psychosis** is used to describe symptoms that affect a person's beliefs, thoughts, feelings and behaviours. Psychosis can cause someone to misinterpret or confuse what is going on around them. For example, a person who is experiencing psychosis may hear voices when alone but the voice is heard internally and so is very real to him/her. When someone becomes unwell in this way it is called a psychotic episode. An episode is a period of time when someone is having symptoms of psychosis that interferes with normal day to day life. Psychosis is most likely to occur in late adolescence or in the early adult years.

Social Cognition refers to how we think in social situations i.e. how we interpret, process, store and apply information we are receiving when interacting with other people in social situations.

Social & Occupational functioning refers to how we function in our day to day lives. There is evidence that a person living with psychosis has challenges interacting in their social environment including contact with family, friends and their wider social group. This can make it difficult to participate in everyday activities like going to school, attending work or simply leaving the house to meet a friend or attend an appointment.

What is involved in taking part in the study?

If you decide to take part in the study you will:

1) Complete a **clinical assessment** where you will be asked questions about your mental health. There will also be some neuropsychological tests which will test things like your memory. This session will last for approximately 2 hours.

2) You will have a **one-hour session** with a therapist once a week for 10-12 weeks. Depending on which arm of the study you are in, these sessions will focus on supporting you in coping with daily life in a variety of ways.

3) After **10-12 weeks** of meeting with the therapist you will repeat the clinical assessment and neuropsychological tests.

4) After **3 months** we will invite you to complete a final session where again we repeat the neuropsychological tests. By repeating these tests, we will have the opportunity to measure your activity over time.

Each participant will be reimbursed €20.00 per assessment session (3 sessions in total).

Risks

There are no risks associated with participating in this study. Your usual treatment team will recommend you to participate in the study. If at any time during the study you become unwell you can withdraw and we will let your treatment team know.

Benefits

We cannot predict improvements in individual participants. You will have the opportunity to provide feedback on your experience of the intervention to assist with developing future interventions.

General Data Protection Regulation

This study is guided by the EU General Data Protection Regulation (GDPR) which came into force in May, 2018. Your identity will remain confidential throughout and after the study. The signed consent form will be stored on site by the principal's investigator and only members of the research team will be granted access to the form. A reference number will be assigned to the participant's name upon participation in the study as part of ensuring confidentiality. This number will be used to identify all material collected from you. Only the research team will have access to the anonymised data from the experiment. These members are bound by a contractual code of secrecy that means that members would face disciplinary action who disclose or facilitate unauthorised access to identifiable data. All other data from the study visits (i.e. the clinical assessment visit, the neuropsychological assessment visit) will be safely stored with Prof. Gary Donohoe, who leads the study, and Emma Frawley at NUI Galway. This data will be analysed at a group level and this will be used in academic publications and presentations. Data will not be analysed at an individual level and it will not be possible to identify individual participants. At the end of this study (After 4 years) the data will be destroyed. If you have any further questions in relation to GDPR please contact the research team (Contact details below).

Conditions and withdrawal

It is entirely up to you if you would like to participate in this study. As a participant of this study, you may voluntarily decide to withdraw at any time without any consequences. In the event that you need to withdraw you only need to contact the research team via email or by phone. A decision not to take part or to withdraw from the study at any time, will not affect your rights in any way and will not impact on your current medical care.

Research Ethics Committee

This study has been approved by the Research Ethics Committee at Galway University Hospital. No persons, who are carrying out this research have a link to the Committee.

Lawful basis for the research

This health research is carried out based on the General Data Protection Regulation (Article 6 and Article 9).

Re-Contact

It is optional for you to be contacted by the same research team for future studies. If you agree the research team will contact you according to your preference via phone or email. If you agree to be contacted for future studies, you do not give consent to future studies. This option does not impact on the participation of this study or any future study.

For further information, please contact: CRESTR@nuigalway.ie or telephone 086 852 7199

The CReSt-R Team:

Prof. Gary Donohoe

Principal Investigator

Emma Frawley

Study Lead

Megan Cowman

Research Assistant

Appendix I: Parent Information Sheet

Letter of Information to Parents

Project Title: Cognitive Remediation & Social Recovery in Early Psychosis (CReSt-R)

About this information leaflet:

You are being asked to allow your child to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. This Participant Information Sheet will tell you about the purpose of the research, along with its potential risks and benefits.

There will be a screening process to ensure that your child is eligible and that it is safe for your child to take part in the study. If eligible, and you and your child agree to take part, we will ask you to sign a consent form. Only the minimum amount of data necessary for the study is being sought. If there is anything that you are not clear about, we will be happy to explain it to you. Please take as much time as you need to read it. You will also be given a copy of this participant information sheet and the consent form to keep. You should only consent to your child participating in this research study when you feel that you understand what is being asked of your child, and you have had enough time to think about your decision.

Description of the study:

This study is researching social cognition and social and occupational functioning in young people aged 16 to 30 living with psychosis. What does this mean?

The word **psychosis** is used to describe symptoms that affect a person's beliefs, thoughts, feelings and behaviours. Psychosis can cause someone to misinterpret or confuse what is going on around them. For example, a person who is experiencing psychosis may hear voices when alone but the voice is heard internally and so is very real to him/her. When someone becomes unwell in this way it is called a psychotic episode. An episode is a period of time when someone is having symptoms of psychosis that interferes with normal day to day life. Psychosis is most likely to occur in late adolescence or in the early adult years.

Social Cognition refers to how we think in social situations i.e. how we interpret, process, store and apply information we are receiving when interacting with other people in social situations.

Social & Occupational functioning refers to how we function in our day to day lives. There is evidence that a person living with psychosis has challenges interacting in their social environment including contact with family, friends and their wider social group. This can make it difficult to participate in everyday activities like going to school, attending work or simply leaving the house to meet a friend or attend an appointment.

There is an **optional** part of this study which will use Electroencephalography, **EEG** for short. An (EEG) is a noninvasive test that records electrical patterns in your brain. It involves wearing a cap with electrodes that measures activity in your brain and sends signals to a computer. We will ask your child to sit for 2

minutes with your eyes open, 2 minutes with your eyes closed and then to complete a simple task for 4 minutes whilst wearing the cap. The procedure is completely painless.

What is involved in taking part in the study?

If your child takes part in the study they will:

1) Complete a **clinical assessment** where they will be asked questions about their mental health. There will also be some neuropsychological tests which will test things like memory. This session will last for approximately 2 hours.

2) They will have a one-hour session with a therapist once a week for 10-12 weeks. Depending on which arm of the study your child is in, these sessions will focus on supporting them in coping with daily life in a variety of ways.

3) After 10-12 weeks of meeting with the therapist they will repeat the clinical assessment and neuropsychological tests.

4) After **3 months** we will invite your child to complete a final session where again we repeat the neuropsychological tests. By repeating these tests, we will have the opportunity to measure your child's activity over time.

Each participant will be reimbursed €20.00 per assessment session (3 sessions in total).

Risks

There are no risks associated with participating in this study. Your usual treatment team will recommend you to participate in the study. If at any time during the study you become unwell you can withdraw and we will let your treatment team know.

Benefits

We cannot predict improvements in individual participants. Your child will have the opportunity to provide feedback on their experience of the intervention to assist with developing future interventions.

General Data Protection Regulation

This study is guided by the EU General Data Protection Regulation (GDPR) which came into force in May, 2018. Your child's identity will remain confidential throughout and after the study. The signed consent form will be stored on site by the principal's investigator and only members of the research team will be granted access to the form. A reference number will be assigned to the participant's name upon participation in the study as part of ensuring confidentiality. This number will be used to identify all material collected from your child. Only the research team will have access to the anonymised data from the experiment. These members are bound by a contractual code of secrecy that means that members would face disciplinary action who disclose or facilitate unauthorised access to identifiable data. All other data from the study visits (i.e. the clinical assessment visit, the neuropsychological assessment visit) will be safely stored with Prof. Gary Donohoe, who leads the study, and Emma Frawley at NUI Galway. This data will be analysed at a group level and this will be used in academic publications and presentations. Data will not be analysed at an individual level and it will not be possible to identify

individual participants. At the end of this study (After 4 years) the data will be destroyed. If you have any further questions in relation to GDPR please contact the research team (Contact details below).

Conditions and withdrawal

It is entirely up to you if you would like your child to participate in this study. As a participant of this study, your child may voluntarily decide to withdraw at any time without any consequences. In the event that your child needs to withdraw you only may contact the research team via email or by phone.

Research Ethics Committee

This study has been approved by the Research Ethics Committee at Galway University Hospital and NUI Galway. No persons, who are carrying out this research have a link to the Committee.

Lawful basis for the research

This health research is carried out based on the General Data Protection Regulation (Article 6 and Article 9).

Re-Contact

It is optional for you to be contacted by the same research team for future studies. If you agree the research team will contact you according to your preference via phone or email. If you agree to be contacted for future studies, you do not give consent to future studies. This option does not impact on the participation of this study or any future study.

For further information, please contact:

Emma Frawley

Arts Millennium Building Extension (AMBE)

NUI Galway

Tel: 353- 91- 492801

Email: emma.frawley@nuigalway.ie

Principle Investigator:

Prof. Gary Donohoe

Arts Millennium Building Extension (AMBE)

NUI Galway

Appendix J: Letter of Consent

Letter of Consent

The purpose of this study - which is to research social cognition and social & occupational functioning – has been explained to me to my satisfaction and I have had an opportunity to read the letter of information.

Participant Initials: _____ Date: _____

Contact details for members of the study team have been made available to me. I have had the opportunity to discuss any questions I may have with the research team, and all questions have been answered to my satisfaction.

Participant Initials: _____ Date: _____

1. I voluntarily agree to participate in this study including completion of the intervention and tests before and after the intervention. I understand that I can drop out at any time, and am not required to give a reason. I understand opting out will not affect my medical care, now or in the future. All research data will be stored at NUI Galway under Prof. Gary Donohoe's lead.

(Circle as appropriate) YES / NO

Participants Initials: _____ Date: _____

2. I understand that my personal details will be kept strictly private and confidential and will only be used for research related to this study.

(Circle as appropriate) YES / NO

Participants Initials: _____ Date: _____

3. I understand that the research team cannot guarantee improvements for individual participants.

(Circle as appropriate) YES / NO

Participants Initials: _____ Date: _____

4. I understand that I am free to withdraw my consent for the study at any time, and either participating in or withdrawing from this study will not affect that any medical or psychological treatment I receive.

(Circle as appropriate) YES / NO

Participants Initials: _____ Date: _____

5. I understand how my data will be obtained, stored and for what purpose under the General Data Protection Regulation (GDPR), 2018.

Participants Initials: _____ Date: _____

6. I agree to have my contact details kept on file, which may be used by the same research team to contact me about future studies. If you agree the research team will contact you according to your preferences via phone or email. I also understand that I do not give consent to future studies by agreeing to be re-contacted for future studies. I understand that this option does not impact on the participation of this study or any future study participation.

(Circle as appropriate) YES / NO

Participants Initials: _____ Date: _____

PARTICIPANT'S NAME: _____

PARTICIPANT'S SIGNATURE: _____

Date: _____

WITNESS'S NAME: _____

WITNESS'S SIGNATURE: _____

Date: _____

Research Team:

Prof. Gary Donohoe

Dept. Psychology,

Room 1040, Arts Millennium Building Extension (AMBE),

NUI Galway.

Tel: 353-91-495122

Email: gary.donohoe@nuigalway.ie

Emma Frawley

Room 1062, Arts Millennium Building Extension (AMBE)

NUI Galway

Tel: 353- 91- 492801

Email: emma.frawley@nuigalway.ie

Appendix K: Letter of Assent

Letter of Assent

The CReSt-R study is researching an intervention which aims to improve social cognition and social & occupational functioning in young people living with psychosis.

As you are under 18 in order for you to take part in this study we require:

(a) Your parent(s) consent
(b) **Your assent** to take part in the study and making sure you understand what exactly is involved if you choose to participate

To provide your assent and to join the study ***please circle*** yes or no to the following questions:

1. I have read and understood the study information sheet	YES	NO
2. I have had the chance to ask questions about the study	YES	NO
3. I understand I can withdraw from the study at any time	YES	NO
4. I understand my information will be kept private unless I or someone I know is at risk	YES	NO

5. I understand I do not have to answer any questions I do not want to YES NO

6. I understand how data (information about me) will be collected, stored, kept safe and for how long under General Data Protection Regulation (GDPR) YES NO

7. **I am willing to take part in this study** **YES** **NO**

Please sign your name below to finish this form:

Signed: _____

Your Name

(Block capitals): _____

Date: _____

Appendix L: CReSt-R Clinician Referral Form

Referral to The Cognitive Remediation & Social Recovery Study (CReSt-R)

NICOG, Department of Psychology, University of Galway

Patient Information (Please circle or delete as appropriate)			
Name	D.O.B		
Address	Tel:		
email	Diagnosis		
Current medications	Adherent to medication	Yes	No
	Cognitive difficulties	Yes	No
If under 18			
Parent/Guardian Name	Tel:		

Clinical Team Information	
Consultant Psychiatrist	Tel:
G.P.	Tel:
Keyworker (If applicable)	Tel:
Other	Tel:

Clinician Checklist (Please circle or delete as appropriate)		
Is this person within the first 5 years of a diagnosed psychotic illness?	Yes	No
Is this person community based & clinically stable?	Yes	No
Does this person have the capacity to give consent?	Yes	No
Does this person have a h/o organic impairment?	Yes	No
Does this person have a h/o head injury with a LOC > 5-minute duration?	Yes	No
Does this person have a documented history of intellectual disability (or IQ<70)?	Yes	No
Has drug abuse been present in the preceding one month?	Yes	No
Has this person consented to being contacted by the research team?	Yes	No
I understand this person may be assigned to the intervention or control arm of the study	Yes	No
I would like a call from the research team to discuss this referral	Yes	No

Signed: **Date:**

Email completed referral forms to CRESTR@nuigalway.ie

Appendix M: Interview Schedule (study 4)

Cognitive Remediation & Social Recovery in Early Psychosis Interview Schedule

1. Intervention content and delivery

1.1 General experience of CReSt-R Intervention

1. Can you tell me about how you found taking part in the program overall?
2. What are the main things, if any, you found most interesting about the program?
3. Was the program what you expected?

   (Prompts- anything that surprised you, anything you did/did not expect?)
4. Was there anything about the therapy experience that you found particularly important or helpful?
5. What things, if any, might you have found difficult about taking part in therapy sessions?
6. Is there anything you would change about the program?
7. How likely would you be to recommend taking part in the program to another individual? Why?

1.2 Intervention components

8. Can you tell me about your experience of using the online CIRCuiTS programme?

   (Prompts- interface, usability, level of difficulty, likes/dislikes, the 'just right' challenge)

9. What was it like to complete the CIRCuiTS programme at home between therapy sessions?

   (Prompts- reminders, frequency, motivation, access to technology/Wi-Fi, was it different from completing it with the therapist)?

10. How was your experience of the second part of the therapy intervention which focused on cognitive behavioural therapy and social recovery?

    (Prompts- strategy use, identifying thoughts, feelings, behaviours, collaborative formulation).

11. Could you describe the therapy intervention in your own words?

    (Prompts- was this explained to you by your therapist? Did it make sense?)

12. If you were aware of two types of therapy did flow well together in your opinion?

    (Prompts- did they make sense together and was the link between them clear to you?)

1.3 Mechanisms of action/change

13. Do you remember **setting goals** in the therapy sessions?

    (Prompts- goals tab in CIRCuiTS programme, SMART goals, personalised goals, meaningful goals).

14. How was your experience of setting goals on the program?

15. Do you think goal setting was an important part of the program?

16. Did you meet the goals you set in therapy?

    (Prompts- can be partially met, smaller goals met, were goals adapted? Were goals not met? Would you have changed your goals? Were your goals your own?)

17. CIRCuiTs cues us to think about how we use **strategies** in everyday life. Do you remember which strategies you identified as most useful during therapy?

    (Prompts- examples of strategies might be chunking, rehearsing, chaining, visual cues, taking notes etc.,)

18. Did the idea of using strategies make sense to you?

    (Prompts- had you thought about strategy use before? Did you call it something else? Was it explained clearly to you?)

19. Did you learn any new strategies during therapy?

    (Prompts- strategy tab in CIRCuiTS, trying things out in everyday tasks)

20. How was your experience of using strategies in therapy and everyday life?

    (Prompts- were they useful? If so, how do you think strategies work to be helpful?)

21. **Metacognition** or 'thinking about thinking' was also a part of this therapy intervention. Was this explained clearly to you by the therapist?

    (Prompts- PRIME- thoughts before, during and after an activity)

22. How motivated did you feel to take part in the therapy sessions?

    (Prompts- was there a difference between motivation completing work with the therapist or on your own? Did anything make you not want to participate? What made you want to participate? Did motivation come from yourself or someone else?

23. What did you think of the overall length of the program?
    (Prompt- number of sessions)
24. How did you find the length of the sessions?

    (Prompts- preference for longer/shorter sessions, more/less than once a week)

25. Did you miss any sessions, if so, how was your experience of re-engaging with therapy?

    (Prompts- communication with therapist re: sessions, re-scheduling of session, assertive outreach)

26. Did you prefer sessions to be held at your home or did you meet the therapist elsewhere?

    (Prompts- preference on location and why, did this make a difference in participation? Behavioural experiments)

27. Did your complete sessions online? If so, how was this experience for you?

    (Prompts- difference to in-person sessions, use of software, benefits. challenges)

28. Do you prefer therapy sessions online or in-person?

29. How was your experience of the ending of therapy?

    (Prompts- follow up support, discussion re: goals, feedback from therapist, would you change anything about the ending of therapy?)

30. Did you feel the therapist was the 'right fit' for you?

    (Prompts- therapeutic rapport, comfort level, would you have changed therapist if that were a possibility)

31. Did this therapy meet your needs?

1.4 Communication between sessions

32. How did you communicate with the therapist?

    (Prompts- email, text, WhatsApp, phone calls)

33. How did you find this experience?

    (Prompts- frequency, too much/too little contact, feelings around initiating contact)

34. Would you change anything about the communication approaches used?

    (Prompts- preference of mode).

2. Trial design, conduct and processes

2.1 Recruitment & retention

35. How were you recruited to the study?

    (Prompts- poster, clinician, service).

36. Can you tell me about this experience?

    (Prompts- initial contact with study team,)

37. Was there anything in particular that made taking part in the program appealing to you?

38. Was there anything that made you not want to take part in the program?
39. What ultimately convinced you to take part in the program?
40. Was enough information provided before taking part in the study?

    (Prompts- information letter, understanding of group allocation, enough time to give consent?)

41. Did you ever consider leaving the study/ending sessions?
    (Prompts- level of wellness, dislike of an aspect of therapy, logistics)
42. What, if anything, encouraged you to continue with sessions?

    (Prompts-perceived benefits, motivation)

43. How could patients/public be more involved in designing this study intervention?

    (Prompts- explain PPI, what aspect would you liked to have given feedback on?)

2.2 Individual Participant Outcomes

44. If you found this therapy helpful, how do you think the specific therapy works to help people recover/meet goals?
    (Prompts- CIRCuiTS component, SRT component, therapeutic rapport, space to talk, assertive outreach)

45. Did this therapy intervention fit in with other aspects of your recovery & health care?
    (Prompts- what was their TAU, did the therapy blend with clinical team goals)

46. What would you change about this therapy intervention?
    (Prompts- recruitment, sessions themselves, the therapist, timing, therapy components)

47. What did you dislike, if anything, about this intervention therapy?

2.3 Outcome assessment measures

49. How was your experience of the assessment sessions?

    (Prompts- timepoints X 3, any feedback on a particular measure that was positive or negative)

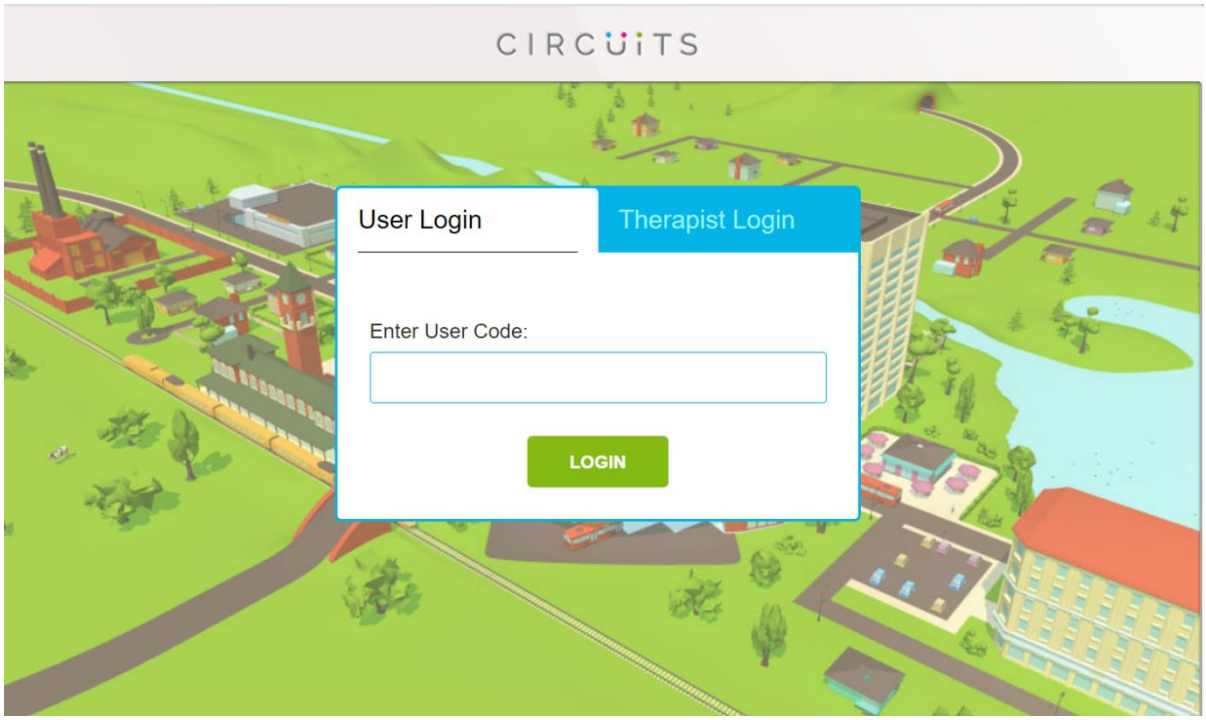
50. Do you think anything else changed for you because of the intervention that we did not capture in the assessment sessions?
    (Prompt- do you think we are measuring the 'right thing'?)

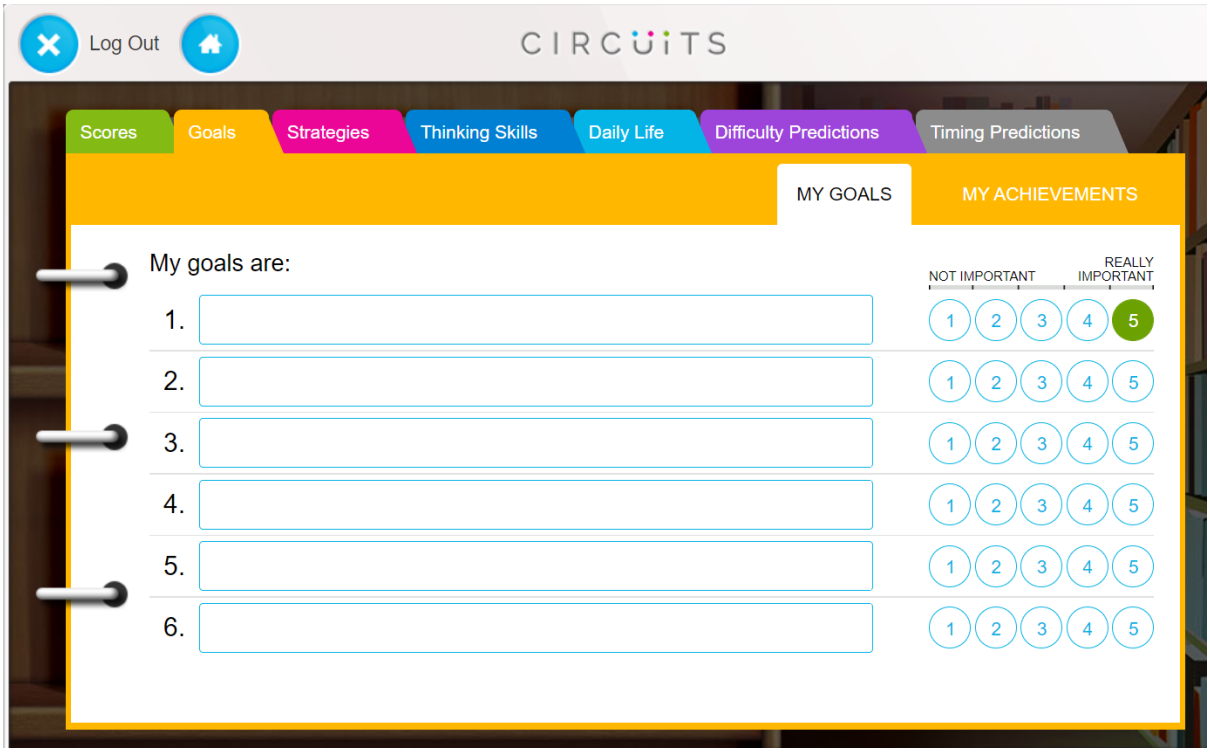
51. Is there anything you would change about the assessment sessions?

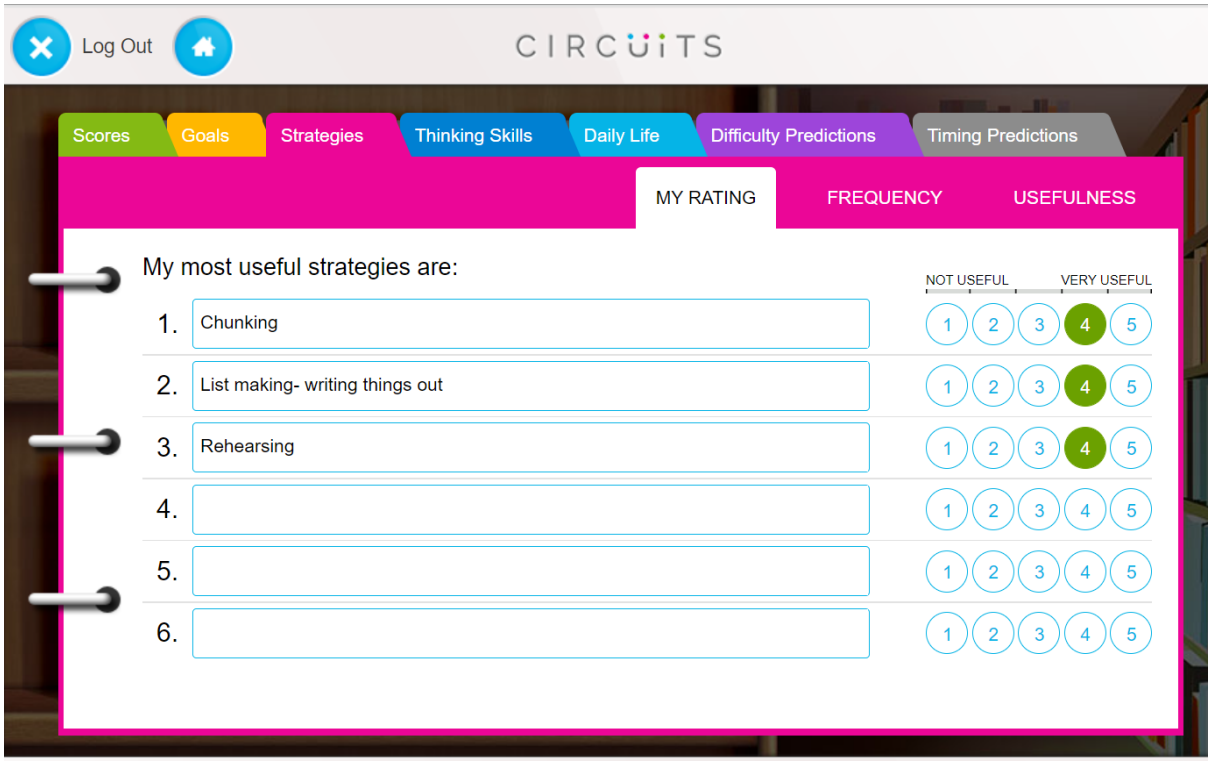
52. If you completed assessment sessions online, how was this experience compared to in-person assessment?
53. Do you prefer online or in-person delivery of the assessment sessions?

54. Is there any other feedback you would like to give on your experience of taking part in the CReSt-R study intervention?

Appendix N: Visual prompts for qualitative interviews (study 4)






Log Out
CIRCUITS
Scores
Goals
Strategies
Thinking Skills
Daily Life
Difficulty Predictions
Timing Predictions
MY RATING
FREQUENCY
USEFULNESS
My most useful strategies are:
NOT USEFUL
VERY USEFUL
1. Chunking
2. List making- writing things out
3. Rehearsing
4.
5.
6.

Appendix O: Initial Coding (study 4)

Name	Coded Text
Timing	yeah you're probably right there. No it probably wasn't the time. I was too busy I suppose. I mean I didn't really wanna think about it myself so I can't say that yeah I wanted to focus too much on it. But probably now yeah probably now would be a better time or is a better time to think about those things. But yeah. Maybe it would be different for different people. So yeah.
Uncertainty	I mean what was the aim of it or what were you looking for when you were doing this?
Understanding strategies	yeah it did make sense but there again like the goals I found it difficult to think of what my strategies were. And I suppose we took a bit of time to think about them which was helpful.

And also knowing how to be more aware of my thoughts and emotions. I felt like I could carry that forward.

And it emerged that one of my behaviours was avoidance that I was avoiding meeting people and talking to people. And just to identify that behaviour was very clarifying for me and then we could begin to challenge it a bit.

Name	Coded Text
Thinking about my thinking 'metacognition'	suppose the most time when I would remember it is if I was really anxious about something. And then I'd sort of go back to the therapy and think well what way can I help myself to reduce the anxiety and then I think of writing things down. But as we went on through the therapy I was able to see you know it clarifies in your mind you know what you're trying to do and then you can begin to work it out and do something about it. But I suppose being aware of my anxiety about different things helps me to manage it better. And you know I suppose I have a fear of facing into new things and being able to be aware of my emotions and thoughts around that and also realising that other people think the same thing about new things as well. That sort of got help where I needed it really. But the other thing we looked at was this you know I can be labelling a bit and that I labelled myself as a psychiatric patient and just to be aware of that I think is very helpful. I can't remember but I know it was an idea that I struggled with for a long time. I don't know. I think at the time it was pretty kind of abstract or a bit unrelatable. I didn't really know what it meant. But she explained it to me but yeah. I think the biggest part and the most helpful part was solving the misconceptions that I had about myself. You know so I tend to catastrophize things a lot, absorb blame from other people and basically just put myself down. And we also identified that mindreading was something that I do a lot as well. So that kind of counteracted the mindreading just being spontaneous. And another thing that I found really helpful from the therapy is just my own awareness of my thoughts an emotions. Like I didn't realise how anxious I was about certain things. I always thought that I wasn't good at knowing what my emotions were because you know I used to talk to a Chaplin when I was in college and I had need for spiritual direction and he was encouraging me to be more aware of my emotions about different things for my own sake and I didn't seem to be getting anywhere with that.

you know maybe I get impatient at times with people or something like that you know write them down. And you kind of took it home and you were looking at it and then I was like yeah actually I could probably work on that you know and give people a bit more time and give people a bit more of myself you know that kind of way.

You mentioned meta cognition and I think it helped me develop that and to think about why I was doing things in certain ways and how I wanted to do things and what would actually help me be more effective in how I was doing things.

Name	Coded Text
Thinking about my thinking 'metacognition'	yeah Emma did talk to me about meta cognition. I wouldn't feel fully familiar with it maybe. But yeah certainly thinking about my thinking I have improved on that.
	Yeah maybe. Well all I remember is kind of writing things out on big A4 sheets and kind of breaking them down, all my thoughts I suppose like breaking them down and being able to look at them from afar and kind of discuss them with Emma.
	I'd describe it as becoming more aware of your thoughts and emotions and learning how to challenge your thinking. Yeah being able to manage on your own with thoughts and emotions a bit better and reduce your anxiety levels.
	I think working on thoughts was the most interesting part for me. I thought circuits was a bit at times it could be a bit dull. But working on thoughts and thinking about thinking that was kind of it kind of helped me out a bit.
	And particularly I suppose the biggest problem that I've always faced other than just the catastrophizing is usually the all or nothing thinking so its either one specific thing or the other, there's no kind of in between. And this is really what helped me kind of develop a sense of pragmatism as I was growing up. And to kind of progress past that is to accept and understand that there is more than just my perspective on that. But writing them down and kind of getting to know yourself a bit better and talking about stuff. It was like a counselling session you know every week which was brilliant. It was really really good.
	I would say it's a therapy program based on cognitions and how your mind works and just how to navigate it and that sort of thing.
	I would say probably the most challenging but still also the most interesting would be the meta cognition. You know so getting behind the reason for the way it is that I think that I think you know where this has come from, how it is I'm using it and how to maybe try and unravel it.

So when she kind of explained different things like the different thoughts, behaviours, actions and the circular kind of diagram she laid out I thought that kind of made a lot of sense. And the other things of like the mechanisms like catastrophizing and those kind of things I thought it all kind of clicked with me these are the things I do

Some of the thoughts I was having I didn't really pay much attention to until it was kind of pointed out to me. I thought that was kind of interesting.

the cognitive behavioural therapy it was I suppose naturally more applied to my everyday life. And it was from that that I sort of began to be more aware of my own thoughts and emotions and anxiety and how to control it.

Name	Coded Text
Thinking about my thinking 'metacognition'	The whole kind of looking at the thoughts and the behaviours and the actions and how they interact with each other and overlap. And working on the goals like you know different things I wanted to do and what was stopping me from doing them or how I was feeling about them and the different ways of thinking, catastrophizing or I can't really remember any of the other ones but how they all made sense at the time. There's kind of a label for these things. A lot of people do them. Just kind of the thoughts behind all these things that go on in my mind or other people's minds. Yeah.
	Well what I focused on with Emma was really the should. Like I'm really that sort of a thinker like I should be here doing this, I should be doing that and all the emotions that kind of come with it.
	It is a strategy I had used but I hadn't really been aware that I was using it at all.
	yeah so I suppose the main skill that I had probably applied and still do practically apply since is the rehearsing of what it is that I have to say or at least that I think that I have to say or for retaining information. Specifically the biggest problem I think as well that I put in there was remembering names. So now when I meet someone new I'll have no problem remembering their face. I'll always remember what they look like but names generally tend to evade me quite a bit. So when I meet someone and they introduce themselves I'll usually repeat their name like four to five times in a row and then maybe I might have to go back and ask once more but after that then I'm usually fine.
	Yeah. I mean I think that's probably something I've taken from it in the longer term. That's probably one of the main things I've taken from it is just to kind of break things down like that, why wouldn't I do that or the challenge and you know challenge the beliefs. Yeah I think that's...
	Yeah. I mean if I do something yeah I'd probably put a bit of pressure on myself yeah.

	I found the platform very straightforward to use. I actually enjoyed using it once I got used to how it worked and everything.
	I would say I really really enjoyed the opportunity
	Ummm... Not about the structure of the program. I really did enjoy that
	I suppose there was like the different tasks or the different things that we had to do every week like the memory test or remembering. I'm trying to remember everything that we did. I suppose I had never done those kinds of test the actual program anything ever like that before so it was different. Yeah.

Name	Coded Text
Therapy can be enjoyable	I feel like I really enjoyed it yeah.
	I found it enjoyable actually.
	I enjoyed doing the study.
Thinking about my thinking 'metacognition'	Its getting you to have a look at how you think and how you do things and how to be able to do those things in the real world.
	Just little things to recognise like how my body reacts to certain things, certain ideas just things like that. The thought behaviour kind of link. Yeah.

	Interviewer: If its okay to ask you would motivation be a challenge for you normally? Interviewee6: Yeah. Interviewer: Okay. So this was a challenge like most other things in life. So at times that was difficult. But then as well sometimes to try and find the time as well to actually sit down and do the exercise every week was. And then if I'm honest there were times where I kind of said okay well I don't know if I wanna do this this week and I would go in without it done. And there would be times I
Therapy can be enjoyable	NO I didn't actually. I didn't. I was enjoying them.

Name	Coded Text
Therapy can be enjoyable	What was it like to try and complete the circuits at home between sessions just on your own? Interviewee1: I enjoyed that. I liked just doing a little bit every day. Yeah it was fun for me really. well I was enjoying it. I was enjoying the therapy for that hour a week and also I was enjoying doing circuits Well I actually enjoyed doing it for forty minutes a day and I like the variety of activities that were in it. some parts of it a little bit challenging which to be honest I found quite enjoyable in the end. It was mostly that I was enjoying it really yeah. Yeah I suppose mostly it was interesting.

	And then Emma was really approachable. I mean we could talk about anything or we could kind of address anything I wanted to do or talk about. Yeah I think that's it really.
Therapy can be challenging	You know it was kind of even thinking of a goal sometimes was difficult because you had to really sit down with yourself and think well where do I wanna be in a month's time, where do I wanna be next week, do I wanna change things. Yeah I thought it was interesting. Social recovery it's a kind of awkward thing to do during lockdown and with Covid going on and that sort of thing. Socially it was hard to kind of figure out what to do from that angle. But yeah I thought the CBT was good. It helped. Well I found some parts of the circuits were kind of mind twisters kind of just a bit kind of well not tough but just a bit difficult at times. Yeah.

Name	Coded Text
Therapy can be challenging	That was okay. There were like I said there were weeks when I came in and it wasn't done. Now it was like doing homework in a sense. In the beginning I found it difficult because I think I was kind of explaining my experience with psychosis and stuff and I found that difficult and upsetting and difficult I think because it was so close. It happened so close to the time that I started the therapy with Emma so I mean I found it difficult to open up about that and to talk about that. but I mean we didn't really focus too much on that either. I thought it was fine. Looking back now I'd say I could have done a bit more but I did what I could at the time. I suppose I found it difficult sometimes to complete the circuits every week you know and it got a bit repetitive and it got a bit boring at times. So that would have been one thing that might have needed changed. Can I check Joe just overall how motivated would you say you were to take part in the sessions like a little bit, a lot, in between? What would you say? Interviewee6: I'd say in between. Yeah in between I'd say.

And also just the fact that I got on very well with Emma that I was able to talk to her very easily was a huge sort of confidence booster to me.

And Emma was very sort of you know very friendly and put me at ease as well. She'd say if the weather was good she'd say you know I hope you're enjoying the good weather and those sort of personal little touches like that made a huge difference at putting me at ease.

And even now she texts me. Like to organise this meeting she texted me and then she would always ask how I was doing and that type of thing you know. And she's very good, very very good.

always felt you know she said that if I needed to check anything out with her during the week that I could always contact her and I felt very much at ease about doing that if I had to.

And then when I met Emma I thought yeah okay I'll do it then because I think probably Emma was the point at which I was like yeah I'll do it because when I met her I was kind of reassured that it would be. She was nice so yeah.

At the time so I think it was just someone to talk to I mean once a week. I think that in itself was reassuring and really nice to have during a stressful time of college and in final year and all that.

Name	Coded Text
Therapeutic rapport	Emma was an incredible or is an incredible therapist. That's just one thing I would say. She's really really very very good natured and very kind and really had an interest in what I was doing and what I wanted to do you know. So that's one thing I would say. And then Megan was great as well. She kind of talked me through how to do the assessment and it really helped. It was really clear you know I think it was coming back in every week and speaking to a therapist. That was definitely it. The human contact you know and meeting somebody in the profession you know that kind of way.
	I did yeah. and Emma had to help me prioritise which goals were more important.
	I suppose confidentiality maybe. Now Emma reassured me of course but you might have a little bit of something in the background saying well is all this gonna be confidential, can I say everything that happened or that's going on in my life and you know that kind of thing. But I was reassured. I was definitely reassured after having talk to Emma you know.

yeah. No any time that I had a problem or a query I was able to reach out to Emma either through WhatsApp and email.

You know every week I was coming in to Emma and talking to her and just with updates. And then I suppose we had a really good chat every time. You know I was there for maybe an hour I think if I can remember right but we had a really good chat every time about just general things about what was going on in my life and how I was adapting to you know maybe being out of hospital or something like that and seeing how things were going and then setting goals as to what I wanted to do in the future and stuff like that you know.

I've seen two different psychiatrists and I tend to say very very little to them about what I'm really thinking or feeling. So I thought it would be a similar experience again and that I just wouldn't be able to express myself very well. So I was really glad that the therapy was going so well and that I was connecting with Emma in that way.

Yeah definitely. She was I felt like she understood what I was saying and she listened very well.

I think probably equally having someone to talk to and then the CBT thinking about that too I think.

Just very understanding and very quick to adapt if needs be.

Name	Coded Text
Therapeutic rapport	I suppose I was surprised that Emma came all the way from Galway to visit me. And that was huge in you know I felt really well treated in that way. I felt that she was investing a lot in me.
	I think Emma was quite good at adapting to my energy levels and my focus.
	I think I preferred in-person ones better when you're talking about kind of personal things to do with being personal.
	suppose like I said I would definitely keep coming in weekly

Therapeutic rapport	NO I think Emma suited me really well because yeah I enjoyed her company anyway.
	It didn't make me feel under pressure either to perform any better but it sort of gave me an extra motivation in a way to get more out of the therapy. Yeah I found that I was touched really that she came all the way and I found that helpful as well.
	It was nice to have Emma there to just even talk to just kind of a support, an extra support for myself. Yeah I mean I felt supported in it really. Yeah.
	So Emma was very gentle in that way with me. She never put any pressure on me to think or feel differently about things.
	Like it suited me because it was so closed to where I was based. It suited me because Emma was really nice to deal with. It suited me at the time because at the time I think I needed someone just to check in with and focus on practical stuff and thinking. I can't really think of anything else. Yeah.
	Ummm... I suppose I felt the fact that I was working with a person who was trying to help me in some way you know that I wanted to respond as best as I could to that.
	OH we got on great. We got on great. Yeah.

Name	Coded Text
Therapeutic rapport	yeah I thought she was very nice.
	Yeah no definitely. We built up a rapport pretty quickly. I think it was maybe finding my third session that I went into kind of more intimate details about myself but the first two sessions we were getting to know each other. There was no problem there. She's a really lovely really bubbly kind of personality. And yeah it was nice chatting to her as well.
	yeah she came to my house. And that was one thing I wanted to improve on as well is having visitors and you know how to make them feel welcome and all of that. And so that was a helpful experience as well to have someone in the house that had never been there before and thinking of how to make them feel welcome and how to talk to them. And I was also anxious about driving and she let me drive her into town so that we could go for a walk together. And she listened to what my thoughts were as I was driving along and that was helpful as well. And actually I think I've been less anxious driving since then.

	I felt that I had learned tools from it
	I found repeating was the main one for me. If I had to memorise something repeating was the big one. Repeating thoughts.
	yeah. Yeah definitely. And as I say even just practicing what it is that I want to say before I say it. So yeah when I'm speaking in Portuguese I'll have to say it to myself what it is and I'm able to say and then rather than having to say it several times I can usually get it almost the first time.
	I don't really remember. I mean if I really thought hard maybe I might but I don't really. Was it things to help me remember?
	And you can apply them in the real world you know.
	And writing things down as well I felt that I could always go back to doing that as well when I needed to.
	And I've used that technique a lot of times since and I've found it much kinder to myself.

Name	Coded Text
Strategy use	So I suppose it basically gives you the techniques that you need to be able to successfully implement whatever tasks it is that you want to do

	I did yeah. and Emma had to help me prioritise which goals were more important.
Strategy use	So in relation to the online tools it was more figuring out my strategies, my strategies for coping and for dealing with different situations and how to tackle some of the different tasks. They were quite beneficial for me. Particularly you know for like memorization skills I had to generally repeat stuff quite a lot or to write it down which was one of my strategies that I ended up using in my last assessment. Yeah. I suppose I'm not sure that I can remember what my strategies were except the one that stands out is writing things down, that I'd remember things better if I write them down. And I suppose even writing things down just to express myself as well and reduce anxiety I've still used that since the therapy. That would be the main thing. yeah so I suppose the main skill that I had probably applied and still do practically apply since is the rehearsing of what it is that I have to say or at least that I think that I have to say or for retaining information. Specifically the biggest problem I think as well that I put in there was remembering names. So now when I meet someone new I'll have no problem remembering their face. I'll always remember what they look like but names generally tend to evade me quite a bit. So when I meet someone and they introduce themselves I'll usually repeat their name like four to five times in a row and then maybe I might have to go back and ask once more but after that then I'm usually fine. Whereas your point about what you're saying the organizational strategies around setting a timetable, planning ahead they were the really key things for you then.

Name	Coded Text
Strategy use	Well they were new to me most of them. They weren't something I actively thought of until I did circuits. So the kind of things that would have come up might have been learning to rehearse things, learning to chunk bits of information, trying to take notes, they would be the common enough sort of strategies. Does any of that ring a bell? Interviewee4: It does actually. And I suppose those three are being employed now as I'm working. Do you know what I mean. You're remembering chunks of information. You've to remember the table numbers because it's all table service now in O'Connor's.

Scaffolding	Were you more motivated in the sessions or were you more motivated when you were working at home by yourself or were both equally motivating? Interviewee3: Probably in the sessions. Yeah so I think that's helped me in a way. And in preparation for doing that I was able to do kind of a part-time FETAC course last year so to kind of step up. And now because of Emma helping me try to arrange supports in NUIG when I was in NUIG I'm now able to go seek the supports I need in Sligo I.T. So I set the goals for what I wanted to achieve within the circuits but then as I came back then the week after Emma explained to me like no these are goals that I wish to have for myself. So I brought them back down on a personal basis. Some of the thoughts I was having I didn't really pay much attention to until it was kind of pointed out to me. I thought that was kind of interesting. yeah. NO they definitely did make sense when Emma had gone through them with me. I would have used rehearsals quite a bit before but in a probably less coherent way or less useful way. I found it very helpful that Emma sort of sometimes she'd put words on things and other times she got me to put words on the things. But I did need some help maybe phrasing them you know. And Emma was helpful at kind of putting words on them but I felt like it was very much expressing what I wanted myself. Emma she was very good at helping me to express myself But when we were talking it through just a few things popped up like getting ready for a course or work or whatever.

Name	Coded Text
Scaffolding	And then I'd chat to Emma about it as well and she'd kind of be asking you know how did you get on with this goal this week. Yeah I suppose it was helpful in that sense because I was able to just keep an eye on things you know. Whereas before I wasn't making any goals at all. I wasn't kind of checking in with somebody every week. Yeah it was just good. And it gave me kind of something to work towards.

Recommending to others	So if I was to describe it informally, very informally obviously you go in every week and you do the circuits. Now I wouldn't say circuits to somebody who didn't know what it was but a computer application in which you kind of look at your goals, you test your memory, you test your different skills online or on the circuits program. and then you go in and you talk about goals and you talk about how your week has been and how you want to develop yourself as you go along. So I would definitely recommend it to people anyway and that's how I'd describe it I suppose. I definitely would recommend it to anybody. Actually to be honest I'd recommend CBT to everybody because it's a great way to get skills that most people have but just don't know how to use or when they can apply them. Yeah I definitely would recommend CBT to anybody. Just to kind of give yourself insight into the way you think. The support of it. Yeah I suppose to make things more manageable in thinking about them. I would say its kind of like coaching and encouragement and support. Interviewer: And coaching and encouragement to do what? Interviewee3: To do the things that I want to do and that would help me lead a life that I want to lead. I would say I really really enjoyed the opportunity. I would have loved to have continued on with the study more. And I would encourage anyone to take part, anyone at all. I would definitely yeah. Yeah. Oh definitely. It would be great to have people who have done the study already to get involved to design it or to help give feedback on how it should be done or you know what worked and what didn't work.

Name	Coded Text

Name	Coded Text
Previous experiences	I suppose it was just the only thing I was doing was going into outpatients and renewing my scripts for medication and that kind of thing and talking to one of the doctors that were there. So that was really the only kind of other sort of care I was getting or recovery that I was doing. But I think between the medication and the CBT that I was doing and coming in every week it was really beneficial you know. I had never done anything like that before and it was just very different. I did my best to stay involved with the services. It was the services that didn't want to stay involved with me. There's a huge difference in how things are run in CAMHS and an adult and I think every service user knows that. And its very very disheartening and demoralizing and sometimes traumatic, just plain traumatic the way they treat you.
Recommending to others	yeah I would definitely recommend it to anyone yeah. Would you recommend to somebody else to take part? Interviewee3: Definitely yeah. Well yeah I think I would. It can help with memory circuits and it can help with the cognition as you said. Yeh I would recommend it yeah. Well it's just helpful to have someone to talk to about your goals and someone to kind of talk you through it, talk you through what you want. Just that's the main point.

Name	Coded Text

Name	Coded Text
Preferred mode of intervention	It was nice because it was close by and just kind of kept things not separate but it was nice to have a space with Emma that you could just go to and you know no-one's coming or going or making noise too much or whatever it was. Yeah.
Previous experiences	Well I wasn't in other treatment for a few months before the program and during the program.
	yeah. Because you're used to one thing and then everything just levels off. And you're expected to have the motivation to keep going but there's no-one to go to. So yeah.
	well I thought when Dr Hallahan said it to me at the time I thought oh he's just gonna put me in a study trial group. I didn't really like him as a doctor so I didn't really think too highly of the things he was saying. So I thought maybe oh he's just, it probably wasn't based on reality but oh he's just using me for a trial there, not a trial but a study. So I would have never really done any CBT or anything like that before. So I didn't know anything about it. I didn't know how it worked. I didn't know anything about it really at all.
	One of the things that would sort of put me off talking to people like if I met neighbours is that I'm sort of so aware that I've been in a psychiatric hospital and I think you know what would they think if they knew that and they'd want to have nothing to do with me.
	I thought maybe I'd be put under pressure to think more positively about everything and I kind of find it difficult to just suddenly you know change my mood and think positively about things.
	I think it did help. Well one of the reasons that I wasn't getting much help from the actual mental health services so that kind of encouraged me to seek out help from the study as well.

That was my preference. Yeah I was happy enough to go into the college. It was grand yeah.

Name	Coded Text
Preferred mode of intervention	No I think worse. I think I was happy enough just to go in. Because it was in town anyway you know.
	Yeah. I mean I didn't experience much online but I don't think it would have had the same affect if it was online.
	Well I suppose I was happy to meet her rather than be over Zoom. But for what we were trying to do I think the Zoom sessions were quite adequate really I think. Yeah I was happy enough with them.
	No I think I would have preferred in-person sessions Definitely.
	It was in college so we mainly met in the college in NUIG in her office or in a room nearby. So I preferred that.
	I think we met in a coffee shop once and I preferred it in the college. I don't think I would have liked it at home or in a hospital setting.
	Hospitals I don't particularly like. Yeah I just find its easier to focus in a different setting.
	I think I preferred in-person ones better when you're talking about kind of personal things to do with being personal.
	Definitely in-person. It's much better.

And I was also anxious about driving and she let me drive her into town so that we could go for a walk together. And she listened to what my thoughts were as I was driving along and that was helpful as well. And actually I think I've been less anxious driving since then.

Name	Coded Text
Personal improvements	suppose the most time when I would remember it is if I was really anxious about something. And then I'd sort of go back to the therapy and think well what way can I help myself to reduce the anxiety and then I think of writing things down.
	I was really surprised when I went to write them down that I could actually express myself very well. And it became clearer what my thoughts and emotions were and then as a result of that I was able to manage them a bit better. They weren't as overwhelming. And even since the therapy once or twice I've written down my thoughts about something that I was anxious about and it has eased the anxiety by a lot.
	I think the biggest part and the most helpful part was solving the misconceptions that I had about myself. You know so I tend to catastrophize things a lot, absorb blame from other people and basically just put myself down. Since doing the therapy I don't do this so much.
	I found that my thinking on the spot improved a bit actually by using circuits. Like there was one time when I was down the road with my parents and a cyclist came behind. And I knew that I needed to communicate to them to move in some way but it just wouldn't come out what I needed to say. And then after a few weeks of using circuits the same scenario happened again and I was able to say immediately you know move to the right. So I think it speeded up my thinking a bit which was helpful.
	And I've used that technique a lot of times since and I've found it much kinder to myself.
	I might do but I'm not sure that it fully captured the progress I had made. Maybe if there were more questions around how you feel around other people or you know how your interactions with other people have changed it might capture the progress a bit better.
Preferred mode of intervention	so we were in the buildings there in NUIG and yeah that was grand. It was a nice quiet little office. There wasn't anyone disturbing us or anything which was nice.

Well I found it good overall. It kind of gave me a bit of a push to get going with whatever course I wanted to do and that sort of thing.

Name	Coded Text
Personal improvements	That might be one way of capturing the progress. Then maybe if there were more questions about how I'm relating to people, how comfortable I feel in people's company you know and go through maybe how I've improved relating to family, how I've improved relating to friends, how I've improved relating to neighbours, How I've improved relating to strangers. If there were questions around that I think it might capture my progress a bit better.
	Just kind of the whole achievement of them I suppose to get things achieved and done. Yeah to achieve these goals that would help me in the long-term in life in general and that would allow me to do more things like you know driving or having the degree or whatever.
	I suppose I think some of my goals were too... I've achieved the goals like the long-term goals. I was talking to Emma a lot about trying to get back into work and I'm working now. And I was talking to Emma about moving out and I've moved out of the home house so now I'm in the town. So the goals actually came around full circle you know.
	I know that my values and goals have changed since the study. It probably did help me in kind of kickstarting or like as a springboard into what I'm doing now. Yeah like when I was doing the study for example part of it was to help me in college because I was doing a diploma in youth work. So I didn't finish that diploma but now I'm just in first year of a sociology and politics degree in Sligo.
	I know that my values and goals have changed since the study. It probably did help me in kickstarting or like as a springboard into what I'm kind of doing now.
	I found that helpful because it helped me to put things in place with the college I was attending at the time. I didn't finish that college course because of Covid and having to move away and everything during Covid. But yeah I found that it help facilitate me in doing the things I needed to do.
	I felt that I had learned tools from it
	has given me confidence and put me at ease with people. I'm not sort of running away anymore.
	But also I don't know was it directly because of that therapy or not but I've definitely improved in the last couple of years in a few different areas related to my mental health. Yeah.

made it clear in my own mind

Name	Coded Text
Personal improvements	You mentioned meta cognition and I think it helped me develop that and to think about why I was doing things in certain ways and how I wanted to do things and what would actually help me be more effective in how I was doing things.
	Yeah. I mean I think that's probably something I've taken from it in the longer term. That's probably one of the main things I've taken from it is just to kind of break things down like that, why wouldn't I do that or the challenge and you know challenge the beliefs. Yeah I think that's...
	yeah I think I still am ready to work or whatever. Yeah.
	Yeah I suppose it was great to look back and see all the progress and how I was developing with the I suppose memory and attention and stuff like that. and I suppose there was a little feeling of well how will I do now without these CBT sessions and that kind of thing you know.
	yeah I mean I saw Dr Hallahan and then I went to the counselor on campus but I mean it probably positively impacted me to give me more understanding maybe in the counselling. I'm more understanding and probably compassion and all that for myself to you know not be so hard on myself and all that.
	Yeah definitely yeah. so I got my driving licence.
	Yeah because I wouldn't have written things down much before that. So that was huge yeah.
	Well I think I did yeah. I did start a course but I went into it head first. The course ultimately didn't work out in the end.

I know that my values and goals have changed since the study. It probably did help me in kind of kickstarting or like as a springboard into what I'm doing now. Yeah like when I was doing the study for example part of it was to help me in college because I was doing a diploma in youth work. So I didn't finish that diploma but now I'm just in first year of a sociology and politics degree in Sligo.

Name	Coded Text
Ownership of Therapy- autonomy	Yeah. yeah definitely. My sessions now would be completely different to another person's sessions you know what I mean. It was tailored so it was perfect.
	yeah you're probably right there. No it probably wasn't the time. I was too busy I suppose. I mean I didn't really wanna think about it myself so I can't say that yeah I wanted to focus too much on it. But probably now yeah probably now would be a better time or is a better time to think about those things. But yeah. Maybe it would be different for different people. So yeah.
	Yeah. I was trying to get my driving licence and driving lessons done. The other things were about college, doing a thesis, setting goals around that, writing it. Yeah they were very practical goals. Like from my point of view they were very based on things I was doing every day and things I wanted to get done. Yeah.
	No they were my goals yeah definitely.
	I kind of felt like they were almost two separate things really. I suppose I found the cognitive behavioural therapy much more helpful really than the circuits. And yeah the circuits seemed to be much more abstract I suppose. The cognitive behavioural therapy got much more into where I was at in terms of thinking and emotions and that. And as I say if that had come earlier on you know closer to me being in hospital I probably wouldn't have responded near as well. Yeah.
	suppose I think every individual has a different journey to make. And if the program had been offered to me a year ago I probably wouldn't have even gone on it. So it depends on the frame of mind that you're in to be even open to the program. It just got me at a very good time.

yeah. I think it would actually be really nice if I still had access to those things because I don't, at the moment I don't think. I don't think I saved any lists or anything of what was done.

Yeah so I think that's helped me in a way. And in preparation for doing that I was able to do kind of a part-time FETAC course last year so to kind of step up. And now because of Emma helping me try to arrange supports in NUIG when I was in NUIG I'm now able to go seek the supports I need in Sligo I.T.

Yeah I suppose it was great to look back and see all the progress and how I was developing with the I suppose memory and attention and stuff like that. and I suppose there was a little feeling of well how will I do now without these CBT sessions and that kind of thing you know.

Name	Coded Text
Moving on	Oh definitely. It would be great to have people who have done the study already to get involved to design it or to help give feedback on how it should be done or you know what worked and what didn't work.
	Yeah. I mean I think that's probably something I've taken from it in the longer term. That's probably one of the main things I've taken from it is just to kind of break things down like that, why wouldn't I do that or the challenge and you know challenge the beliefs. Yeah I think that's...
	I know that my values and goals have changed since the study. It probably did help me in kickstarting or like as a springboard into what I'm kind of doing now.
	I feel like it could have been very helpful to keep having access to it after the therapy was done.
	Emma made a list of the things. You know she asked me what things I might like to carry on forward after the therapy and we made a list of the things that I could still work on. And then I shared that list with the occupational therapist so that she'd be aware of the things that I'd like to continue to work on in the immediate future. And also the occupational therapist rang Emma to talk to her as well and the same list sort of emerged from that conversation as well.
	And the therapy had basically given me the way to not because I'm not looking at myself so negatively or I'm not looking at my life as being unmanageable that I can take the progress you know towards making these steps and having the confidence to do so.
	A little bit of anxiety. Its nothing too severe but it was just kind of well how will I get on now, I'm on my own you know that sort of feeling.

	I suppose I think some of my goals were too... I've achieved the goals like the long-term goals. I was talking to Emma a lot about trying to get back into work and I'm working now. And I was talking to Emma about moving out and I've moved out of the home house so now I'm in the town. So the goals actually came around full circle you know.
Goal setting is challenging	You know it was kind of even thinking of a goal sometimes was difficult because you had to really sit down with yourself and think well where do I wanna be in a month's time, where do I wanna be next week, do I wanna change things.

Name	Coded Text
Goal setting is challenging	When I made the first three I didn't really know whether they were specifically for me. So I set them more as in goals that I wanted. This was in the online circuits. So I set the goals for what I wanted to achieve within the circuits but then as I came back then the week after Emma explained to me like no these are goals that I wish to have for myself. So I brought them back down on a personal basis. I found it difficult to think of what to put down as goals. I hadn't really thought about what my goals could be what could be achievable. So initially it kind of took me a bit to get into it to think of the goals. And a few times I might think of an idea and then when I go to say it I forget what I was going to say as well so I found that a bit difficult I found it very difficult initially to come up with ideas of what I wanted to do. But when we were talking it through just a few things popped up like getting ready for a course or work or whatever. I suppose when I look at a blank page like that I find it difficult to think of things to work with. Like maybe if there were prompts or something or even if we went through examples of what other people's goals were. I don't know would that mean that you mightn't get to what your individual goals are but
Moving on	To be honest a little bit sad because I was kind of eager to kind of do more. Yeah. For me it felt like I was taking my first few steps up the stairs and I just wanted to start running then at that point.

	Its hard to say because... Well yeah the experience of goal setting was important but the actual goals maybe not so much because I had very different ideas of what I wanted.
	I mean I didn't have to think too hard about my goals. They were very kind of practical goals.
	I did yeah. and Emma had to help me prioritise which goals were more important.
	At the time Emma was helping me get through some college things by setting goals and that. so the goal setting component was helpful.

Name	Coded Text
Goal setting	And then I suppose the kind of goals/actions, working towards something well various things. I'm not sure if I did much working towards the goals but it was kind of laying them all out to kind of look at and assess and explore different ways of going about goals or different actions involved and the thoughts behind them as well. If I wasn't up to something and why wasn't I doing it or why couldn't I approach it or you know the thoughts behind it too so breaking it down that way was really good. Like it was really helpful.
	And I feel like my goals were reached quite well at the end of the therapy so I was happy about that.
	I think the biggest thing for me was that it was goal orientated.
	I suppose I could actually find day to day that I was doing better with... You know I kind of had a goal in mind. I think there was weekly goals and then there was kind of monthly goals or something that I wanted to achieve next year or something like that. And then I'd chat to Emma about it as well and she'd kind of be asking you know how did you get on with this goal this week. Yeah I suppose it was helpful in that sense because I was able to just keep an eye on things you know. Whereas before I wasn't making any goals at all. I wasn't kind of checking in with somebody every week. Yeah it was just good.
	I found it helpful that we set goals at the beginning of what outcomes I'd like from the therapy.

	The circuits, seeing the progress on the circuits.
Goal setting	Yeah. I was trying to get my driving licence and driving lessons done. The other things were about college, doing a thesis, setting goals around that, writing it. Yeah they were very practical goals. Like from my point of view they were very based on things I was doing every day and things I wanted to get done. Yeah. Yeah so big actual steps since I've started this therapy. And kind of looking at it as more of a five year ten year kind of goals rather than just solely immediate goals. The more immediate goals were for the social aspect of things. There was two or three goals I think I had. One was to be ready for a course or work when I decide to do it. And the other was to be able to read a book. I can't remember what the third one was but those were two of the main ones.

Name	Coded Text
Goal setting	So we were actually talking about the goals and then typing them into circuits and then I could look at them at home when I was at home and I could you know see how those goals changed every week you know what I mean. setting goals as to what I wanted to do in the future and stuff like that you know. it was fantastic because it actually mapped it out for me and I knew okay well... And it wasn't like a homework sort of thing. It was kind of more relaxed and it was like not putting pressure on myself but it was more I suppose well that goal is there, is it possible, is that achievable, can I do that. initially I was sceptical and I thought you know we'll set goals and I'll never be able to reach them. I think you really just have to be honest with yourself. And I think they're called SMART goals you know the goals that are achievable and realistic and you can do them in the right period of time and that kind of thing I think that's huge. It just gives you. You know it's not too hard on yourself and it's not too easy on yourself as well. Like get up and make a cup of tea sometimes that can be difficult for somebody but for others it might be very easy you know.

I think about a 7 out of 10. I was more intrigued. It was intrigue more than anything. Because I remember I was in outpatients in Galway here and somebody just mentioned it to me would you be interested in working in this study. And I think it was Megan that was there.

I think just at the time I just wanted to try different things that would maybe help me. I didn't know how they would help me but yeah.

I hadn't heard of anyone doing a similar study. I remember seeing a poster for it in one of the colleges and I just thought it sounded really interesting that it was looking at early psychosis in 18-30 year olds. And the fact that the therapy was it was almost like a computer game.

Feedback is motivating

yeah. But I liked how you could see the graphs of how you were progressing in that.

Yeah. I like seeing data and its nice to just see things laid out in front of you.

Name	Coded Text
Feedback is motivating	Well I liked the improvements that I was starting to see and while I was doing it I noticed in myself I could remember just as part of circuits there was certain word lists you had to remember or sequences of numbers. I can remember them a bit better now. Yeah I suppose it was. It was very structured you know and I suppose we could see as the weeks went on how well I was doing in it and how I was improving and that kind of thing. So that was helpful. I would very much like to have feedback about was there an improvement like my results at the start and my results at the end. It would have been nice to see did I actually improve. But that's just an interesting thing that I would have liked to have known. I suppose it was good in a way because you could map it all the way. This was the thing that was very good about it. You could map the whole way and see how you were doing and to see a rating out of 1-5 how easy it was, how difficult it was, how you know interesting it was. You know you could log it every week an then you could put a note on the side if you wanted to so that was very handy.

And I wasn't expecting that that it would meet my needs. I didn't think that a therapy could really do that.

As I said beforehand I didn't really have much of an idea what was going to happen. But as soon as we had our initial assessments Emma explained it very well what was gonna happen that there was two different types of therapy and I was going to be in group one or group two or whichever it was at the time and what would have been covered then in our group would have been different to the other groups and how exactly we were gonna achieve that. Yeah. Absolutely was happy with everything she told me about.

I had never done anything like that before and it was just very different.

I had no real idea. I suppose I thought it was gonna be something... what would I say? What did I think it was going to be?

I think my mother. She'd always ask me when's your next appointment and that sort of thing so that kind of motivated me a bit to stick with it.

I had only really heard of CBT kind of in passing over a few years from friends who had done it. And basically every one of them all told me the same thing, you're going to have homework to do which I was like my first thought was like that's going to be me being sent back to secondary school kind of homework and I was like na. It wasn't any way daunting or time-consuming really you know.

I just kind of saw it as an extra help and like an extra help in some kind of way. So I thought anything I can do that will help me whether it be just in the short-term or long-term I'll give it a go and see how it goes. Yeah I thought it would just help in some way. I didn't know what way or would it or if it would but I thought it just would help.

I mean I don't think I had any expectations of it. I didn't really know what I was getting myself into. Not in a bad way but I just didn't really know. I just thought there might be kind of a therapeutical approach to it so I said I'd just do it anyway and see how it goes.

Name	Coded Text
Expectations of therapy	I suppose confidentiality maybe. Now Emma reassured me of course but you might have a little bit of something in the background saying well is all this gonna be confidential, can I say everything that happened or that's going on in my life and you know that kind of thing. But I was reassured. I was definitely reassured after having talk to Emma you know. I suppose it was yeah. I was kind of just you know I would like research and academic sides of things you know. So you know to do a study in NUIG was quite big you know. I suppose there was like the different tasks or the different things that we had to do every week like the memory test or remembering. I'm trying to remember everything that we did. I suppose I had never done those kinds of test the actual program anything ever like that before so it was different. Yeah.

Ummm... I was surprised that it was extremely practical. I didn't go into it knowing what to expect but the actual exercises that we were doing in the therapy seemed very practical.

Well I didn't know what I was getting into when I first got referred to it but yeah I thought it was good. I thought it was more or less what I expected from therapy yeah.

yeah I suppose I was afraid that you know the therapist would be disappointed with me that I wouldn't talk enough. And I was also afraid that I might be put under pressure to think positively or do things that I felt were overwhelming.

Yeah I was immediately interested in it. I suppose I thought you know it might be helpful in some way. I wasn't sure what way it could be helpful but I thought you know I'll try it.

I wasn't sure what to expect really. I didn't think that we'd be doing as many sort of abstract things in circuits you know like finding patterns with different things and memory work and that sort of thing. And then with the cognitive behavioural therapy I suppose I thought maybe I'd be put under pressure to think more positively about everything and I kind of find it difficult to just suddenly you know change my mood and think positively about things.

So I would have never really done any CBT or anything like that before. So I didn't know anything about it. I didn't know how it worked. I didn't know anything about it really at all.

I was really interested to get involved with it because as I said I knew myself that I would have to do CBT as part of my study so it was a great way for me to kind of get ahead of the curve. Yeah it was a great experience to amerce myself in.

I didn't really know what to expect. I didn't know what cognitive behavioural therapy was. And I suppose things like that I wouldn't really look them up much myself on the internet. I'd prefer to get sort of a summary from a professional of what it is. So maybe something like that might have been helpful.

I think more information about the content of what you'd actually do on the study would have been nice.

Name	Coded Text
Expectations of therapy	It was pretty clear what was expected of me.
	Yeah. As soon as I got the information sheet I think. Now it was a while ago. I don't remember it but I think it was alright yeah.

Expectations of therapy	If it wasn't very flexible I don't think I would have taken part in it. Or if it was too intensive I don't think so. Like if I compare it to a DBT study that I took part in it was very very intensive. There was a lot of information and it was very overwhelming.
	initially I was sceptical and I thought you know we'll set goals and I'll never be able to reach them.
	It sounded interesting but also the fact that part of it was paid because I was struggling with money at the time.
	It wasn't what I expected no.
	Just when I got the email describing what it was about I just got interested in it. The recovery from psychosis that was the main point that kind of hooked me in.
	Like it was free therapy and it was the vouchers for the actual assessments.
	Once I rang they explained it very clearly. I felt that there wasn't much information about what would actually happen on the poster. But once I rang about it I was given information.
	So yeah I suppose the therapy certainly exceeded my expectations. I was more worried about my own contribution to it would I be able to get into it in the way that the therapist would like me to get involved in it and that.
	So then I was really intrigued about it and I suppose then I just got into it I suppose. Yeah.

Name	Coded Text
Expectations of therapy	To be honest I didn't have much expectations of it because I didn't really know what exactly it was going to involve.

Well I found some parts of the circuits were kind of mind twisters kind of just a bit kind of well not tough but just a bit difficult at times. Yeah.

Maybe now this is just a little thing but just the design elements of the circuits they were a bit kind of they seemed very childish at times.

Fine. I don't think I had any problems. I think I don't know if it was Emma or if I just set aside I don't know 10 minutes or 10 minutes a week or I'm not sure how long I did it but it never took me that long and it was always kind of easy to fit in and to do.

It was fun. It was engaging. I did try and kind of meter it down to about an hour at a time. Yeah. I mean most of the puzzles they are pretty fun. And once you kind of get absorbed into it you just keep going and going and going. I think I ended up passing two or three stages in one sitting. Yeah so it is quite engaging. And for me it was more just to push myself to try and beat my own scores because I'm my only competitor in this game other than the parameters of the challenge really.
I thought circuits was a bit at times it could be a bit dull.

I found the platform very straightforward to use. I actually enjoyed using it once I got used to how it worked and everything.

But I would change maybe some aspects of the actual circuits. I don't know. Some of them were quite easy. Some of them were quite maybe confusing as well at times. Make it as clear as possible but then challenging as well at the same time.

It was pretty not boring just mundane or it was just very all the tasks were pretty similar. The levels changed a bit but yeah it was pretty easy I would say. But then it got a bit harder but it was pretty easy. Yeah.

Name	Coded Text

Changes to be made	I suppose I found it difficult sometimes to complete the circuits every week you know and it got a bit repetitive and it got a bit boring at times. So that would have been one thing that might have needed changed. I remember a different program I did a DBT program that was sixteen weeks and I know there's a standard DBT program which is like kind of six months or a year. I know they're very different but I think something... Like that was quite intensive as well and circuits less so but perhaps... Well definitely longer than three months I think would be ideal. I mean maybe I don't know what the time but maybe I would have liked to talk a small bit about the actual psychosis because I didn't understand anything about it. No-one explained to me anything about it. But I would change maybe some aspects of the actual circuits. I don't know. Some of them were quite easy. Some of them were quite maybe confusing as well at times. Make it as clear as possible but then challenging as well at the same time. I would say for myself a little bit too little in terms of more the one to one. But I know CBT is usually between six to ten weeks depending. But I think myself probably I could do with maybe a year.
CIRCuiTS experience	Some parts of it were. Some parts of it were easy, very easy. It depends on what I was doing what kind of part of the mind I was focusing on whether it was memory or concentration or that sort of thing. Yeah. I suppose it was good in a way because you could map it all the way. This was the thing that was very good about it. You could map the whole way and see how you were doing and to see a rating out of 1-5 how easy it was, how difficult it was, how you know interesting it was. You know you could log it every week an then you could put a note on the side if you wanted to so that was very handy. Like I said some of the exercises were quite easy to the point where you were doing it and nearly I suppose not really paying attention and you'd nearly get some of them wrong because you found it so easy.

Name	Coded Text
CIRCuiTS experience	Well I liked the improvements that I was starting to see and while I was doing it I noticed in myself I could remember just as part of circuits there was certain word lists you had to remember or sequences of numbers. I can remember them a bit better now.

Name	Coded Text
Changes to be made	To be honest I'd say make the challenges a bit harder particularly at the start. I know its kind of designed as well for people who have no background really in I.T or no background in gaming and that's why I did appreciate the more harder version but even a harder hard version would be good, more of a challenge. To be honest I would say vary the questions, vary the scenarios and stuff that are given between the initial the middle and the final section. Because I think yeah when I did all three, all the different questions, all the challenges, all the answers and stuff were practically the same. Some of them I could remember from when I had done the initial assessment. Not about the structure of the program. I really did enjoy that. More just on the technical side of things. I did notice there was small graphical glitches throughout the program. Small things. Just little spelling bits here and there. Maybe like more focusing on I know it was probably very self-directed and all that from my point of view, well I felt I was kind of directing it and leading the sessions. But then I don't think I really explored things that happened before the psychosis or during the psychosis or anything like that. It was very present and it was very action orientated and goals. But there wasn't much exploration of anything in the past. But then again I didn't bring it into that direction either so I can't say it was anyone's fault. I would very much like to have feedback about was there an improvement like my results at the start and my results at the end. It would have been nice to see did I actually improve. But that's just an interesting thing that I would have liked to have known. I suppose like it would be helpful maybe if the person who is conducting the clinical assessment if they could sort of notice maybe the change in that I was much more spontaneous or that I was much more talkative if they could note that that I was much easier in expressing myself in the second clinical assessment. That might be one way of capturing the progress. Then maybe if there were more questions about how I'm relating to people, how comfortable I feel in people's company you know and go through maybe how I've improved relating to family, how I've improved relating to friends, how I've improved relating to neighbours, How I've improved relating to strangers. If there were questions around that I think it might capture my progress a bit better. I think just to make it longer. I think if there was less emphases on assessing the sort of things that we did in circuits the more abstract things and memory and sort of finding patterns. I didn't understand why I was asked to sort of identify emotions in people a lot. Because for me I don't think that's something I struggle with so I was kind of surprised that there was such an emphasis on identifying emotions. But maybe for other people that might be important so just for me I thought I wondered about that.

Name	Coded Text

Name	Coded Text
Assessement experience	Well I found them difficult. They were difficult tests. That's all I can really say about them.
	it was fine yeah. It was fine. At the end of it I was probably tired. There was a lot of thinking.
	I remember them alright. You wouldn't forget them. They were difficult. Some of them were very hard. The first time we did it we were in the college and the second time we did it it was online. So I think it was a bit harder to do it online because you know with internet problems and stuff like that and sometimes its more difficult. And then you had to take a screenshot of the picture you drew or something like that you know. But overall very very challenging and very good. Some of them were very very difficult you know but really interesting as well. So I actually enjoyed that a lot those assessments.
	I mean I didn't really understand why they were asking a lot of different things or the tasks and stuff like the whole patterns and filling in the patterns and how much time I spend in my week doing this and that. In relation to the therapy I mean it was all my functioning wasn't it really like wasn't it all my different functioning's.
	it was very mentally exhausting to do the assessments especially the last one I did I think. The very last one was on Zoom because of Covid and everything so it was a very different structure I thought. Yeah.
Changes to be made	It would have been nice if it was a bit longer but I don't know if that's something you were considering or not.
	yeah. Please. And when the study gets published it would be nice to find out where you can access it more.

Initial Coding for CReSt-R

Code Name	Coded Text
Affirmation from Therapist is encouraging	And I was talking to Emma about one conversation I had and she praised me for being spontaneous.
	I suppose like it would be helpful maybe if the person who is conducting the clinical assessment if they could sort of notice maybe the change in that I was much more spontaneous or that I was much more talkative if they could note that that I was much easier in expressing myself in the second clinical assessment. That might be one way of capturing the progress. Then maybe if there were more questions about how I'm relating to people, how comfortable I feel in people's company you know and go through maybe how I've improved relating to family, how I've improved relating to friends, how I've improved relating to neighbours, How I've improved relating to strangers. If there were questions around that I think it might capture my progress a bit better.
Assessement experience	When we did the middle assessment in the session I had to split it up over two because I was working and in college at the same time so I was a little bit drained
	To be honest I would say vary the questions, vary the scenarios and stuff that are given between the initial the middle and the final section. Because I think yeah when I did all three, all the different questions, all the challenges, all the answers and stuff were practically the same. Some of them I could remember from when I had done the initial assessment. Like when there was the assessments at the start and end I remember the second time I did it over two sessions when it was on Zoom because I couldn't focus for the full lot of assessments.

Name	Coded Text
Understanding the flow of therapy	Well I mean it made sense that they were together. Like kind of the goal to recover from psychosis and cognition is a big part of that and CBT is a big part of that too so I presume yeah they did kind of. They were very different but they did work for what they did. Yeah they worked.

Understanding the flow of therapy

Oh yeah. yeah I thought they flowed yeah.

They did flow quite well together but for me it was nearly two separate kind of things. Because on one side you know I see the online stuff was more kind of brain training stuff you know like testing your memory, testing recognition. Whereas at least the personal therapy its more of an internal kind of assessment that you're looking at you know like what's going on inside of you rather than how it is you do things. But it did eventually tie back to you know how it is that I do things. Yeah they did. I suppose yeah they did actually tie very very well together but for the most part they felt as kind of separate activities.

Maybe if there was a better link between circuits and the cognitive behavioural therapy if I could see more of a connection between the two. Or even if I could be told maybe what is it in circuits that's helpful you know why am I doing these activities in circuits, what are they trying to help. That would be helpful as well.

Very well because we always talked about them first. You know we'd have a general chat about how things were going and then we'd get straight into the circuits with Emma. You know they were balanced very well because then we were looking at different goals and typing them into circuits. So we were actually talking about the goals and then typing them into circuits and then I could look at them at home when I was at home and I could you know see how those goals changed every week you know what I mean.

I thought they were very different yeah, two different things.

I think I sometimes struggled to stay on top of doing it as frequently as I was supposed to.

I'm not sure. I think I remember them being quite distinctive.

Appendix P: Theme construction (study 4)

Coding FEB 15th	Coding March 2nd	Themes
Timing is individual	Timing is individual	**It's an individual trajectory/pathway to recovery/growth**
Therapy can be enjoyable	Therapy can be enjoyable	
Therapy can be challenging	Therapy can be challenging	
Personal Improvements	Personal Improvements	
Moving on after therapy	Moving on after therapy	
Recommending to others	Recommending to others	
Therapeutic Rapport	Therapeutic Rapport - Someone to listen - A safe space - Affirmation	**A strong foundation**
Seeing progress is motivating	Feedback is motivating	
Strategies	Strategies	**The tailored toolkit** **(Mechanisms of action, choosing your tools)**
Ownership of therapy-autonomy	Merged with goal setting	
Goal Setting	Goal setting - Goal setting can be challenging	
Thinking about thinking-metacognition	Thinking about thinking - Clarity	
Previous Experiences	Previous experiences	**Knowledge/ movement of knowledge/flow of knowledge**
Expectations of therapy	Expectations of therapy	
Understanding the flow of therapy	Understanding the bridge between therapies	
Continued uncertainty	Continued learning	

Scaffolding	Scaffolding	
Assessment experience	Assessment experience	**Pragmatic feedback**
CIRCuiTS Experience	CIRCuiTS Experience	
Changes to be made	Changes to be made	
Delivery of Therapy	Delivery of Therapy	
SRT Experience	SRT Experience	

Appendix Q: Description of YOULEAD collaborative projects

Co-developing the YOULEAD Youth Advisory Panel

In May 2019, I co-developed the YOULEAD Youth Advisory Panel with fellow trainee, Emer Conneely. This was a significant piece of work which had a primary goal of consulting with young people regarding youth mental health research being carried out as part of the Youlead program. This body of work involved recruiting young people, developing policies and procedures and co-facilitating YAP meetings. There were a number of key activities with the YAP. A significant output to date is the creation of a spoken word piece which was created in collaboration with YAP members, a local theatre company, and Spunout.ie. Names of contributors are contained in the credits of the final piece, available here:

https://www.youtube.com/watch?v=Wuz-XE8hCao

National Placement with See Change

I completed a placement with See Change**,** Ireland's organisation dedicated to ending mental health stigma. Their work is informed by people with lived experiences of mental health difficulties, who are best placed to give insight into mental health stigma and discrimination. The primary aim of this research project was to expand upon existing See Change data collected in 2017 with a renewed focus on severe and enduring mental illness. The newly acquired data was intended to provide an Irish perspective and link with both the National Office for Suicide Preventions recommendations and Anti Stigma Alliance work in the area of severe and enduring mental illness. An evaluation of the placement from mine and the placement supervisor's perspective follows:

Placement Evaluation by Student

Name of Student: Emma Frawley

Name of Organisation: See Change

Description of Placement

This placement began at the end of January 2020 with a proposed timeline to complete in March. It was remote in nature with communication via email and phone. There was a delay with the timeline of the placement secondary to COVID-19 restrictions. Work carried out for this placement included creation of a survey on the lime survey platform and completion of a written report. The results of the survey and report were reviewed in an online meeting with the placement supervisor, Barbara Brennan and her See Change team.

Reflection on Placement

The area of stigma, particularly in the area of severe and enduring mental illness, is an interest of mine and directly relevant to my PhD study. This placement was beneficial in developing skills in terms of developing a survey on the limesurvey platform, this platform and use of same was new for me. The statistics presented were basic and descriptive in nature secondary to the data being used to communicate with the public. I also completed a thematic analysis on one of the questions and spent time discussing this approach with colleagues and researching this methodological approach. The primary output of this placement was a written report summarising findings of the survey. I found striking the balance between an academic piece of writing and writing something accessible to the public/a non-academic audience challenging. Statistical analysis and disseminating research are areas I will continue to work on, particularly for my international placement in 4th year.

The placement supervisor, Barbara Brennan, was enthusiastic and supportive throughout the placement with open communication. She was very responsive to any queries and supportive with changes arising as a result of COVID 19.

Overall, this was a very positive learning experience and contributed to developing core skills that will translate to other areas of my research.

Placement Evaluation by Supervisor

YOULEAD PhD Placement 2019/2020
Placement Evaluation by Supervisor

Name of Student: Emma Frawley

Name of Organisation: See Change (A project of Shine)

Name of Placement Supervisor: Barbara Brennan

Please enter a number between 1 and 5 after each section, where 1 = Poor and 5 = Excellent. All comments welcome

1.	Attitude to Work:	5
2.	Initiative:	5
3.	Quality of Work:	5
4.	Volume of Work:	5
5.	Communication Skills	
	Written:	5
	Oral:	5
6.	Team-working Skills:	N/A
7.	Attendance:	N/A
8.	Punctuality:	N/A
9.	Overall Assessment:	5

Any additional information, comments or suggestions?

Emma was very enthusiastic from the start. She engaged fully with us, and took into account the different aspects we discussed before approaching the work. Emma amalgamated numerous different parts of our work to produce an interesting and helpful research piece. Her understanding of the topic was evident in the quality of the output – her comments and suggestions on presentation were on-point, and will help guide the next piece of research we engage with. It was a pleasure working with Emma on this placement.

Signed (Supervisor): Barbara Brennan

Date: 29/04/2020