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EXPLORING THE EFFECTIVENESS AND IMPLEMENTATION OF GOAL-SETTING TECHNIQUES IN DIABETES SELF-MANAGEMENT INTERVENTIONS AND STRUCTURED EDUCATION PROGRAMME

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BSc. (Psychology and Neuroscience), MSc. (Health and Social Psychology)

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Submitted September 2018

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Declaration

I declare that this thesis has not been submitted as an exercise at this or any other university.

I declare that this thesis is entirely my own work.

Signed: _____

Milou Fredrix

Statement of contribution

The candidate was responsible for the design, data collection, analysis and write-up of each of the three studies conducted in this research. The supervisory team, Graduate Research Committee, and local experts advised and provided support in conducting the research.

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Abstract

Background. The treatment of diabetes consists of ongoing medical care and continuous self-management. Sub-optimal levels of diabetic control are commonly detected in people with diabetes. Therefore, Healthcare Professionals (HCPs) should aim to inform, educate and support people with diabetes on a continuous basis. 'Collaborative goal-setting with patients' has been identified as a HCP priority behaviour for diabetes research. Goal-setting techniques are widely recommended for diabetes self-management support. However, evidence is lacking regarding the effectiveness and implementation of goal-setting techniques in a diabetes context.

Aim: This research aimed to explore the effectiveness and implementation of goal-setting techniques in diabetes self-management interventions and to explore the implementation of goal-setting techniques in the 'Dose Adjustment for Normal Eating' programme (DAFNE), a prominent Type 1 Diabetes Self-Management Education (DSME) programme.

Methods. A combination of quantitative and qualitative methods was utilised. In study 1, a systematic review and meta-analysis was conducted to identify an evidence base related to goal-setting interventions targeting diabetes outcomes. Study 2 explored how goal-setting is currently implemented in healthcare by assessing the active content and fidelity of delivery of the goal-setting component of DAFNE. A descriptive and observational design was used in which content from the manual of DAFNE's goal-setting component was specified in terms of Behaviour Change Techniques (BCTs) and fidelity was assessed by comparing manual specified BCTs, with corresponding observations of DAFNE sessions. Study 3 utilised a qualitative design to explore DAFNE educators' (HCPs) perspectives on the implementation and operationalisation

of goal-setting in DAFNE and DSME programmes. Themes were identified through an inductive thematic analysis.

Findings. The systematic review found some evidence suggesting that goal-setting interventions have a positive effect on blood glucose levels in people with diabetes. The content analysis of DAFNE's goal-setting component identified 13 different BCTs (operationalised 41 times) within DAFNE's delivery manuals. On average, 57.8% of these BCTs were delivered in practice with large variation across sessions, educators and BCTs. Five main themes were identified in the data from the qualitative interviews with DAFNE educators: 'People need a plan', discussing goal-setting's importance; 'the power of the group', highlighting the impact a group format has on goal-setting practices; 'diversity and individuality', discussing differences in DAFNE participants' and educators' engagement with goal-setting; 'goal-setting's fit', exploring concerns regarding goal-setting's fit within DSME and follow-up care; and 'feelings of inadequate psychological knowledge', describing perceived challenges in delivering goal-setting content.

Conclusion. The findings of this research contribute to a clearer understanding of HCPs' goal-setting behaviour in a diabetes context. While results should be approached with caution, the findings from the systematic review suggest that implementing goal-setting within diabetes support is beneficial. However, results from the fidelity and qualitative studies highlighted that issues can arise when implementing goal-setting. While DAFNE educators saw benefits in goal-setting, concerns were raised regarding goal-setting's current fit within DSME and follow-up care. Furthermore, additional training opportunities were considered valuable for implementing goal-setting strategies. For successful implementation of goal-setting strategies in diabetes care, optimising training and offering continuous support for HCPs seems advisable.

PhD Requirements

This PhD was in accordance with the guidelines for an article-based PhD, as set by the School of Psychology at the National University of Ireland, Galway (Appendix XIV).

Requirements for an article based PhD were met in this thesis, as these state that three articles should make up the core of the PhD, with 2 of these articles accepted for publication and the third submitted for review.

Research outputs

The following manuscripts published or submitted for publication form the empirical chapters in the current thesis.

Published

Fredrix, M., McSharry, J., Flannery, C., Dinneen, S., & Byrne, M. (2018). Goal-setting in diabetes self-management: A systematic review and meta-analysis examining content and effectiveness of goal-setting interventions. *Psychology & health*, *33*(8), 955-977. doi: 10.1080/08870446.2018.1432760

Fredrix, M., Byrne, M., Dinneen, S., McSharry, J. (2018). 'It's an important part, but I am not quite sure that it is working': educators' perspectives on the implementation of goal-setting within the 'DAFNE' diabetes structured education programme. *Diabetic Medicine*, *36*(1), 80-87. doi: 10.1111/dme.13813

Submitted for publication

Fredrix, M., Byrne, M., Carr, E., McSharry, J. Goal-setting in DAFNE; A content and fidelity exploration of the goal-setting component of a type 1, diabetes self-management programme. Submitted to: *Health Education Research* (submitted April 2018).

Conference and Seminar Presentations Associated with this research

Fredrix, M., Byrne, M., McSharry, J. (2015). Exploring the effectiveness and implementation of goal-setting techniques in diabetes self-management interventions and structured education programme. *Innovations in Health Psychology Conference*, Galway, Ireland.

Fredrix, M., Byrne, M., McSharry, J. (2015). Exploring the effectiveness and implementation of goal-setting techniques in diabetes self-management interventions. *Health Behaviour Change Research Group Seminar Series*, Galway, Ireland.

Fredrix, M., McSharry, J., Flannery, C., Dinneen, S., & Byrne, M. (2016). Goal-setting in diabetes self-management: A systematic review and meta-analysis examining content and effectiveness of goal-setting interventions. *Psychology Health and Medicine Conference,* Cork, Ireland.

Fredrix, M., McSharry, J., Flannery, C., Dinneen, S., & Byrne, M. (2016). Goal-setting in diabetes self-management: A systematic review and meta-analysis examining content and effectiveness of goal-setting interventions. *European Health Psychology Society/ Division of Health Psychology Conference,* Aberdeen, United Kingdom.

Fredrix, M., Tang, M. Y., Marques, M., Olander, E., Lorencatto, F., & Mc Sharry, J. (2016). Systematic reviews of behaviour change interventions: using BCT taxonomies for evidence synthesis symposium. *European Health Psychology Society/ Division of Health Psychology Conference*, Aberdeen, United Kingdom.

Fredrix, M., Byrne, M., McSharry, J. (2016). Exploring the effectiveness and implementation of goal-setting techniques in diabetes self-management interventions and structured education programme. *DAFNE PLUS project advisory board meeting*, York, United Kingdom.

O'Hara, M. C., Cunningham, A., Heverin, C., O'Sullivan, E., Burke, H., Fredrix, M., O'Donnell, M., Cantillon, P., & Dinneen, S. F. (2016). 'You can't judge a man until you walk a mile in his shoes': experiential learning in diabetes self-

management increases empathy of undergraduate medical students. Diabetic Medicine, 33(Suppl 1), 322. doi:0.1111/dme.30_13048

Fredrix, M., McSharry, J., & Byrne, M. (2017). Update on behavioural research priorities in diabetes: Goal-setting, attending structured education and measuring what matters. *National University of Ireland, Galway: School of Psychology Seminar Series.* Galway, Ireland.

Fredrix, M., McSharry, J., Flannery, C., Dinneen, S., & Byrne, M. (2017). Goal-setting in diabetes self-management: A systematic review and meta-analysis examining content and effectiveness of goal-setting interventions. *Cochrane Conference,* Galway, Ireland.

Fredrix, M., Byrne, M., Carr, E., McSharry, J. (2017). Goal-setting in DAFNE; A content and fidelity exploration of the goal-setting component of a type 1, diabetes self-management programme. *SPHeRE Network 3rd Annual Conference,* Dublin, Ireland.

Fredrix, M., Byrne, M., Carr, E., McSharry, J. (2017). Goal-setting in DAFNE; A content and fidelity exploration of the goal-setting component of a type 1, diabetes self-management programme. *Psychology Health and Medicine Conference,* Dublin, Ireland.

Fredrix, M., Byrne, M., Carr, E., McSharry, J. (2017). Goal-setting in DAFNE; A content and fidelity exploration of the goal-setting component of a type 1, diabetes self-management programme. *Annual Meeting & Scientific Sessions of the Society of Behavioral Medicine,* San Diego, United States.

Fredrix, M., Byrne, M., McSharry, J. (2017). Exploring the effectiveness and implementation of goal-setting techniques in diabetes self-management interventions. *Population Health Research and Health Service Research (PHR*

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Fredrix, M., Byrne, M., Carr, E., McSharry, J. (2018). Goal-setting in DAFNE; A content and fidelity exploration of the goal-setting component of a type 1, diabetes self-management programme. *Association for Researchers in Psychology and Health Conference*, Tilburg, the Netherlands.

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McSharry, J., Fredrix M. (2018). Health psychology research in Galway, Ireland: creating evidence for effective behaviour change. *Laboratoire GRePS Seminar Series.* Lyon, France

Fredrix, M., Byrne, M., Dinneen, S., McSharry, J. (2018) 'It's an important part, but I am not quite sure that it is working': Educators' perspectives on the implementation of goal-setting within the DAFNE Diabetes Structured Education programme. *European Health Psychology Society Conference*, Galway, Ireland.

Additional manuscripts and outputs

The following reports, manuscripts and outputs are co-authored by the author of this PhD and are related to the current research but are not included as empirical chapters in this thesis.

Published

Mc Sharry, J., Fredrix, M., Hynes, L., & Byrne, M. (2016). Prioritising target behaviours for research in diabetes: Using the nominal group technique to achieve consensus from key stakeholders. *Research involvement and engagement, 2*(1), 14. doi:10.1186/s40900-016-0028-9

Submitted for publication

Flannery, C., Fredrix, M., Olander, E., McAuliffe, F., Byrne, M., Kearney, P.M. Physical activity interventions for overweight and obesity during pregnancy: A systematic review of behaviour change interventions. Submitted to: *Obesity Reviews* (Submitted 30th July 2018).

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List of Abbreviations

BCT	Behaviour Change Technique
BCTTv1	Behaviour Change Technique Taxonomy-version1
BMI	Body Mass Index
COREQ	Consolidated Criteria for Reporting Qualitative Research
DAFNE	Dose Adjustment for Normal Eating
DSME	Diabetes Self-Management Education
HbA1c	Haemoglobin A1c
HCP	Healthcare Professional
HSE	Health Service Executive
MRC	Medical Research Council
NICE	National Institute for Health and Care Excellence
PRISMA	Preferred Reporting Items for Systematic-Reviews and Meta-Analyses
PROSPERO	International Prospective Register of Systematic Reviews
RCT	Randomised Controlled Trials
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
TA	Thematic Analysis

1. Introduction

1.1 Chapter overview

This chapter will introduce the key themes of the research conducted, including an overview of Diabetes Mellitus, how it is managed, and how psychology has contributed to the management of diabetes. Furthermore, the process of involving stakeholders in determining this project's research focus, 'goal-setting in diabetes self-management', will be described in detail. The theoretical aspects of goal-setting and how goal-setting strategies have been implemented within the area of behaviour change and diabetes care will be discussed. Finally, the rationale for the current research will be presented, followed by the thesis outline.

1.2 Diabetes Mellitus

Diabetes mellitus refers to a group of metabolic illnesses characterised by chronic elevated blood glucose levels, resulting from defects in insulin discharge, insulin action, or both (Craig, Hattersley, & Donaghue, 2009). As one of the most common metabolic disorders in the world, an estimated 425 million people are living with diabetes globally, of which 141,500 adults are located within the Republic of Ireland (International Diabetes Federation, 2017). As the sixth leading global cause of disability in 2015 (Vos et al., 2016), diabetes is responsible for overwhelming costs to global health economies (Seuring, Archangelidi, & Suhrcke, 2015). Furthermore the prevalence of diabetes has risen continuously within recent decades, and diabetes is expected to affect 10.4 percent of adults worldwide within the next twenty years (Ogurtsova et al., 2017). Diabetes can take several forms, some of which are more prevalent than others. The two principal types are Type 1 and Type 2 Diabetes Mellitus.

1.2.1 Type 1 Diabetes Mellitus.

Type 1 Diabetes Mellitus (T1DM) is an auto-immune disease, resulting in the full destruction of insulin-producing beta cells in the pancreas. Insulin is required for the body to convert glucose into energy, and is therefore responsible for regulating glucose levels in people's blood (Daneman, 2006). To maintain overall healthy levels of blood glucose, also known as glycaemic control, people with T1DM are therefore required to self-administer insulin on a regular basis, via injections or insulin pumps (Daneman, 2006).

T1DM accounts for only 5–10% of all cases of diabetes. However, it usually emerges earlier in life than type 2 diabetes and is therefore responsible for 90% of diabetes instances in the paediatric age-group (Dabelea et al., 2014). Data from the United Kingdom suggests that the occurrence of T1DM is increasing by about four percent each year (Patterson et al., 2009), with diagnoses in children under the age of five rising more quickly (Hsia et al., 2009). While the cause for developing T1DM remains unknown, research suggests that genetic factors are most likely at play (Daneman, 2006; Patterson et al., 2009).

If not treated properly, T1DM can lead to significant short-term and long-term health complications. Short-term complications include hypoglycaemia or hyperglycaemia, referring to severely low or high blood glucose levels and ketoacidosis, referring to high levels of blood acids called ketones. Long term complications can include retinopathy with potential blindness, nephropathy which could lead to kidney failure and neuropathy which increases risks of foot ulcers and potential amputations (Alberti & Zimmet, 1998). Furthermore, the risk of a cardiovascular event for people diagnosed with T1DM is ten times greater compared to non-diabetic populations of a similar age (Dabelea et al., 2014).

1.2.2 Type 2 Diabetes Mellitus.

Type 2 Diabetes Mellitus (T2DM) is characterised by the inability of the pancreatic beta cells to produce sufficient levels of insulin (insulin deficiency) or by the body's inability to effectively utilise produced insulin to convert glucose into energy, due to insulin resistance in the target organs (NCD Risk Factor Collaboration, 2016). In its early stages, T2DM can sometimes be treated by tackling the body's insulin resistance through exercise and weight loss, which have been shown to make the body more responsive to its own insulin (Fonseca, 2009). To address insulin resistance, people with T2DM are often prescribed oral medication to manage their blood glucose levels. However, unlike T1DM, T2DM is a progressive illness, and functioning pancreatic beta cells respond to insulin resistance by secreting more insulin, causing beta cells to exhaust over time and lose functionality (Fonseca, 2009). Therefore, complete pancreatic beta cell failure typically occurs within ten years of T2DM onset (UK Prospective Diabetes Study Group, 1995), causing people with T2DM to be dependent on insulin injections in order to achieve glycaemic control (Stratton et al., 2000).

The exact cause of T2DM remains unclear, but associated risk factors have been well established. T2DM typically develops in adults over the age of 45. Additionally, overweight or obesity, an unhealthy diet, a sedentary lifestyle and chronic stress are commonly linked to T2DM onset (NCD Risk Factor Collaboration, 2016). While unmodifiable factors as genetic predisposition and family history are at play, research has suggested that T2DM can be prevented in up to 58 percent of cases by changing lifestyles and behaviours (Lindström et al., 2006; Vijan, 2010). Partly due to the increasing worldwide prevalence of obesity (Guariguata et al., 2014), the prevalence of T2DM is increasing drastically (Aguiree et al., 2013), with over 400 million adults

currently diagnosed, and 628 million adults expected to be diagnosed with this condition by 2040 (International Diabetes Federation, 2017).

1.3 Treatment of Diabetes

Effective treatment for diabetes includes ongoing medical care and continuing self-management behaviours by the patient (Ahola & Groop, 2013; Funnell, Tang, & Anderson, 2007). Barlow, Wright, Sheasby, Turner, and Hainsworth (2002) describe self-management as an individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes that characterise living with a chronic illness. Successful self-management requires the establishment of an active and constant process of self-regulation to monitor one's condition and to implement necessary cognitive, emotional, and behavioural responses.

Diabetes self-management is a demanding and multifaceted task, comprising of a variety of self-care activities and skill sets (American Diabetes Association, 2014), that are key to maintaining ones health and quality of life (Ahola & Groop, 2013; American Diabetes Association, 2014; Barlow et al., 2002). Grant et al. (2013) recently identified six key areas of T1DM self-management behaviours: "carbohydrate counting and awareness; insulin dose adjustment; self-monitoring of blood glucose; managing hypo- and hyperglycaemia; managing equipment and injection sites; and accessing health care" (p.728). Examples of specific behaviours within these key areas include: reading food labels to familiarise oneself with nutritional content; counting carbohydrate content within food and adjusting quick-acting insulin accordingly; continuously monitoring blood glucose levels before meals or after hyper- and hypo-glycaemia; and accessing healthcare by scheduling and attending diabetes clinic appointments (Grant et al., 2013). People with T2DM adhere to similar self-care responsibilities to achieve optimum glycaemic control. T2DM self-management tasks

include: lifestyle modifications, such as adhering to a diet and exercise regimen, and monitoring weight; continuous self-monitoring of blood glucose levels; foot care; and the administration of oral medication and progressively, injecting insulin (Vijan, 2010). Overall, self-management of diabetes aims to reduce mortality, short-term and long-term diabetes-related complications, and increase people's quality of life (Chiang, Kirkman, Laffel, & Peters, 2014; Inzucchi et al., 2012).

Engagement with self-management behaviours is key to achieving optimal glycaemic control. Glycaemic control is typically measured in glycated haemoglobin (HbA1C), which is a molecular by-product of the reaction between glucose and haemoglobin molecules within red blood cells (World Health Organization, 2011). The percentage of glycated haemoglobin in the blood is an indication of one's average blood glucose concentration over the last ninety days (Goldstein et al., 2004; World Health Organization, 2011), making HbA1C the most reliable measure of long-term glycaemic control. Guidelines suggest that HbA1C levels equal to or less than 7% in the United States (Chiang et al., 2014) or 6.5% in the United Kingdom for T1DM (National Clinical Guideline Centre UK, 2015) and 6.5-7.0% for T2DM (National Clinical Guideline Centre UK, 2015) indicate satisfactory glycaemic control. Higher levels of HbA1c are associated with greater risks of developing diabetes-related complications (Buell, Kermah, & Davidson, 2007; Kilpatrick, Rigby, & Atkin, 2009; Stratton et al., 2000), and research suggests that a one percent increase in HbA1C, doubles an individual's risk of damage to the retina as a result of diabetes (Lind, 2009).

Over the last two decades, self-management has progressed from being discussed as a standardised and strict regimen to a more personalised and flexible one (Nathan & Group, 2014). In recent years numerous advances have been made in the areas of insulin manufacturing (Flood, 2006), mobile technology (Free et al., 2013),

medical devices such as blood glucose pumps (Bergenstal et al., 2010), intervention development (Nathan & Group, 2014) and self-management education (Funnell et al., 2007). These advances have led to greater potential for people living with diabetes to achieve better glycaemic control while maintaining their quality of life (Grant et al., 2013).

1.3.1 Engagement with self-management.

Despite the known benefits of careful adherence to a diabetes treatment regimen, and the numerous advances that have been made in the area of self-management, less than desirable levels of glycaemic control are commonly detected in people with diabetes (Aguiree et al., 2013; Ahola & Groop, 2013; Aiello et al., 2013; Health and Social Care Information Centre UK, 2013). Research shows that adherence to treatment regimens among people with diabetes is low in comparison to other chronic illnesses. A meta-analysis comparing adherence rates across chronic illnesses, as measured through physical test, medical record, but mainly self-reports, revealed that rates of adherence to self-management were second lowest among people with diabetes (T1 and T2), at 68%, compared to for example 88% in HIV disease (DiMatteo, 2004). Furthermore, independent medical data from the UK reveals that only 27 percent of people with T1DM and 65 percent of people with T2DM meet the recommended glucose control targets (NHS, 2014). These data highlight the need for advances in care, including a focus on behavioural and psychosocial approaches to improve disease management.

Psychological research in diabetes has contributed significantly to the understanding of diabetes self-management (Hunter, 2016) by identifying personal and interpersonal factors that can influence engagement in self-management behaviours. A large-scale review by Ahola and Groop (2013), recently identified several barriers that people with diabetes might face in managing their illness. Personal barriers included:

insufficient knowledge and assimilation of information; motivational problems due to a lack of self-efficacy or holding inaccurate health-beliefs; and not feeling empowered enough to self-manage their diabetes. Additionally, a lack of coping and problem solving skills, potentially due to a lack of barrier identification or inappropriate goal-setting, was discussed as a barrier to self-management. Furthermore interpersonal and environmental barriers were highlighted such as a lack of social support or family conflicts (Anderson & Wolpert, 2004), and access to healthcare and a lack of healthcare professional (HCP) support (Ahola & Groop, 2013; Heisler & Piette, 2005; Tang, Brown, Funnell, & Anderson, 2008). Many of these identified barriers and determinants of self-management behaviours are well-described within psychological models that have been applied frequently to self-management behaviours.

One of the most prominent models used to explain self-management in diabetes is the health belief model (Rosenstock, Strecher, & Becker, 1988). The theoretical base for the health belief model is the assumption that peoples' behaviour is determined on a personal level by an interaction between an individual's incentives and expectancies. In diabetes self-management, an individual's incentives are based on beliefs about the perceived risks and severity of diabetes, and how susceptible they are to these risks. Expectancies refer to their beliefs about perceived costs and benefits of behaviour change and engaging in self-management behaviours. Providing people with information regarding self-management incentives and expectancies, depending on the way in which it is delivered, may alter people's beliefs regarding self-management. However, a meta-analysis by Mazzuca (1982) found that just improving patient knowledge alone is rarely sufficient to improve adherence to treatment regimen in chronic illnesses. The health belief model is therefore underpinned by the concept of self-efficacy (Bandura, 1977), referring to an individual's belief in his or her ability to

achieve certain goals. The health belief model suggests that, people are more likely to engage with self-management behaviour if, people not only expect self-management to prevent serious complications of diabetes, to which they are susceptible, but also believe that they are capable of performing these self-management behaviours (Brownlee-Duffeck et al., 1987). Diabetes support strategies addressing people's knowledge and beliefs about the incentives and expectancies of self-management behaviours, such as HCP consultations and education, combined with efforts to advance self-efficacy, have thus been shown to lead to better results in improving self-management (Jalilian, Motlagh, Solhi, & Gharibnavaz, 2014; Piri, 2010).

Additionally, models such as the Theory of Planned Behaviour have expanding on the views of the health belief model by emphasising social aspects of behaviour (Ajzen, 1991; Shankar, Conner, & Bodansky, 2007) . The Theory of Planned Behaviour claims that in addition to someone's own attitude towards self-management behaviour, someone's views of social pressure to engage in this behaviour, and whether one is motivated to comply with this pressure (wishing the approval of others such as family or HCPs) is of equal importance (Ajzen, 1991). Theories such as the Theory of Planned Behaviour highlight the importance of aspects such as social support or HCP support to warrant people with diabetes' inclination to engage in self-management behaviours. Furthermore, studies have suggested that perceived support from family and particularly from HCPs is an important resource for individuals' adjustment to diabetes and reduce diabetes related distress (Karlsen, Oftedal, & Bru, 2012). This increased understanding of personal and interpersonal determinants of self-management behaviours have led to significant advances in diabetes self-management support.

1.4 Diabetes self-management support

People living with diabetes become their own principal caregivers, and are responsible for self-management and day-to-day lifestyle choices such as adhering, or not adhering to medication, monitoring their condition, recognising a decline in control and deciding on which actions they will take (Aguiree et al., 2013). However, as people are confronted with many barriers to optimal self-management, a certain level of self-management support is essential (Taylor et al., 2014). Bodenheimer, Wagner, and Grumbach (2002) define self-management support as "collaboratively helping patients and their families acquire the skills and confidence to manage their chronic illness, providing self-management tools (eg, glucometers, diets, and referrals to community resources), and routinely assessing problems and accomplishments" (p. 1772). Self-management support has advanced significantly in recent years by incorporating knowledge from psychological and behaviour research. This has led to an increased focus on person-centred approaches in diabetes care, and the implementation of behaviour change strategies and addressing psychosocial barriers to behaviour change in intervention development (Glasgow et al., 1999; Hunter, 2016).

A range of strategies have been implemented worldwide to support people with diabetes including individual or group based education (Norris, Lau, Smith, Schmid, & Engelgau, 2002); behavioural or counselling strategies (Winkley, Landau, Eisler, & Ismail, 2006); and social support programmes (Tang et al., 2008). One area that is evolving significantly is behaviour change interventions (Newman, Steed, & Mulligan, 2004). Changing behaviour is essential in the treatment of diabetes, and efforts by health services to target behaviours which help prevent and manage diabetes are therefore vital to effectively deal with increasing numbers of patients and rising costs (Newman et al., 2004). Therefore, guided by psychological models, numerous

interventions have been developed in which both the behaviours of people with diabetes (e.g. monitoring blood glucose levels) and HCPs' behaviours (e.g. implementing foot-screening programmes) have been targeted (Karter et al., 2001; McCabe, Stevenson, & Dolan, 1998; Michie, van Stralen, & West, 2011). Increasing evidence shows that systematically designed interventions targeting behaviour change can be effective in improving outcomes in diabetes (Avery, Flynn, Van Wersch, Sniehotta, & Trenell, 2012; Michie et al., 2011; Weinger et al., 2011).

1.4.1 Health Care Professional support.

While self-management support can be drawn from many sources such as behaviour change interventions, a large basis of support that people with diabetes rely on is HCP support (Healthy Ireland, 2017; Taylor et al., 2014). Ultimately, people with diabetes are responsible for their own self-management behaviours. However, since diabetes is a lifelong chronic disease involving frequent consultations with HCPs, the healthcare service is therefore one support system that could influence diabetic outcomes significantly. Due to its characteristic early onset, and complexity of its self-management regimen, this is particularly true for T1DM (Daneman, 2006; Karlsen et al., 2012). The role of HCPs is to inform, educate and support people with diabetes to change beliefs and ensure that positive behaviours and coping strategies are enabled and reinforced, and that decisions are (medically) appropriate and taken with confidence (Funnell & Anderson, 2004).

Traditionally, healthcare systems were suited to deliver acute, symptom-driven care, in which HCPs were considered the authority figures, responsible for patients' diagnoses, treatments, and outcome experiences (De Sutter, De Maeseneer, & Boeckxstaens, 2013). This model is not ideal for treating chronic illnesses such as diabetes, which require more continuous support and collaborative life-long care.

Influenced by knowledge from behaviour science and psychology, Bodenheimer, Wagner, et al. (2002) designed the chronic care model. This model highlights the difference in care requirements between acute ill and chronically ill people. This approach to chronic care recognised that people with diabetes are primarily in control of and responsible for daily self-management of their illness and that, self-management plans therefore need to fit with patients' own goals, priorities, and way of life as well as with their clinical needs. It is up to HCPs, to assist people with diabetes in making informed decisions to achieve their goals and overcome barriers through education, appropriate care recommendations, expert advice, and support (Bodenheimer, Lorig, Holman, & Grumbach, 2002; Bodenheimer, Wagner, et al., 2002; Funnell & Anderson, 2004). Diabetes healthcare is thus arguably most effective when shaped as a collaboration between equals in which HCPs are responsible for the knowledge and expertise about diabetes treatment, and people with diabetes for the expertise on their own lives and what works best for them. Based on the chronic care model (Bodenheimer, Wagner, et al., 2002), Battersby et al. (2010) recommend HCPs adhere to a number of principles when providing self-management support in primary care, and highlight the importance of engaging in shared decision-making and collaborative goal-setting. Furthermore, Battersby et al. (2010) suggest taking a non-judgmental approach when engaging with patients, and making an effort to increase patient confidence to be important.

The need for shared decision making and creating self-management plans that fit with patients' own goals and priorities is underpinned by 'Self-Determination Theory' (Ryan & Deci, 2000, 2000). Self-determination theory is a theory of human motivation that focusses on the extent to which behaviours are relatively autonomous (the extent to which behaviours initiate from the self) versus relatively controlled (the extent to which

behaviours are pressured or forced by intrapsychic or interpersonal forces). Self-determination theory assumes that an individual is more likely to be motivated to engage in behaviours if that individual views those behaviours as personally meaningful. In a diabetes context, autonomy motivation refers to the extent to which people with diabetes feel that they are initiating and valuing specific diabetes self-management behaviours (Williams, Rodin, Ryan, Grolnick, & Deci, 1998).

In health care, person-centred care and self-determination theory are often combined with the term ‘empowerment’ (Anderson et al., 1995; Feste & Anderson, 1995). This concept is concerned with increasing patients’ autonomy and sense of control. In line with the chronic care model, the focus of empowerment is to enhance the strengths and potentials of people with diabetes and to make sure they are more involved in healthcare and that their needs are attended to. The philosophy of empowerment recognises that autonomy support is crucial and that patients' goals, objectives, and capabilities must guide the development of diabetes self-management plans in order to be effective (Feste & Anderson, 1995; Funnell et al., 2007). Research indicates that people with diabetes whose HCPs support autonomy motivation and engage in more shared decision making, become more internally motivated to regulate their blood glucose levels and feel more capable at glucose monitoring. Furthermore, they show improvements in their HbA1C (Williams et al., 1998).

Clinical guidelines for diabetes management highlight this need for person-centred and collaborative care (Inzucchi et al., 2012). However, issues with communication between HCPs and people with diabetes are repeatedly reported, such as a lack of empathy from HCPs, differences in views on wellbeing and health between the HCP and the person living with diabetes, and differences in diabetes management goals (Campbell et al., 2003; Ho, Berggren, & Dahlborg-Lyckhage, 2010). A potential reason

for this discordance could be that the treatment of chronic illnesses such as diabetes could be challenging for HCPs, as day-to-day care lies in the hands of the patient, and HCPs could feel frustrated or disheartened when people with diabetes are disinclined to follow medical advice or do not accomplish desired outcomes (Funnell & Anderson, 2004). In addition, HCPs are encouraged to understand how an individual can be supported, not just physiologically, but psychologically and socially as well (Haas et al., 2013). This is arguably a challenging process, as HCPs need to be careful how they perceive compliance and how they increase internal motivation, stimulate behaviour change and provide support (Taylor et al., 2014). While challenging, person-centred self-management support by HCPs is key to effective and person-centred diabetes care. In fact, in a systematic review of self-management support interventions, Taylor et al. (2014) found that the most effective interventions are complex, multi-faceted and tailored to individuals, while underpinned by a collaborative relationship with a HCP within a healthcare system that promotes self-management.

Diabetes support has been advancing in various manners such as an increased focus on behaviour change and person-centred care. While overall levels of glycaemic control have improved in recent years, engagement with self-management remains suboptimal, particularly in T1DM (NHS, 2014). Additionally, implementation issues surrounding collaborative care practices are frequently reported (Bodenheimer & Handley, 2009). Therefore further research and improved evidenced-based practices are warranted to optimise support strategies and improve health outcomes (Hunter, 2016).

1.5 Determining the research focus: Research Prioritisation

Increasing evidence shows that targeting behaviour change in people with diabetes and HCPs can improve outcomes in diabetes (Avery et al., 2012; Weinger et al., 2011). However, a wide range of behaviours are involved in the management of

diabetes, both in people with diabetes and HCPs. Furthermore, a range of available support sources and intervention strategies are available (Norris, Engelgau, & Narayan, 2001). This can make it difficult for clinicians, researchers and intervention designers alike to know how best to focus possible research projects and interventions. Moreover research often does not address the themes that are of importance to members of the public and HCPs (Partridge & Scadding, 2004). Seeking the views of stakeholders by working with people with diabetes, healthcare providers, and policy makers to prioritise research topics, could be a suitable way to decide on a shared research focus (Buckley, Grant, Tincello, Wagg, & Firkins, 2010; Partridge & Scadding, 2004). These stakeholder involvement strategies are being increasingly implemented within health research (Rashid, Thomas, Shaw, & Leng, 2017). A recent systematic review investigated the impact of patient and public involvement on health and social care research and found evidence of the positive impacts of stakeholder involvement in all research stages, including the development of research objectives (Brett et al., 2014).

In addition to developing appropriate research objectives, stakeholder engagement may aid the implementation of research findings into routine diabetes care, which can be a major challenge for researchers due to the constraints of the healthcare system (Colagiuri, 2009; Glasgow, Klesges, Dzewaltowski, Bull, & Estabrooks, 2004; Grimshaw, Eccles, Lavis, Hill, & Squires, 2012). Previous research has identified a lack of stakeholder involvement and diabetes community links as crucial barriers to the implementation of diabetes research into healthcare practices (de Quevedo, Siminerio, L'Heveder, & Narayan, 2012). Therefore, it seems advisable that stakeholder involvement should be a key part of determining a research agenda. However, despite this growing emphasis on stakeholder involvement in health research, few studies describe stakeholder involvement within the area of diabetes.

A key feature of this PhD was that the topic focus was a priority area identified by stakeholders. In 2014, Mc Sharry, Fredrix, Hynes, and Byrne (2016) conducted a research prioritisation exercise at the National University of Ireland, Galway. The aim of this exercise was to identify and achieve consensus on shared priority areas for behavioural research in diabetes in Ireland by involving diabetes stakeholders. The study was part of a programme of research looking to develop two behaviour change intervention programmes in diabetes in Ireland: one focusing on a behaviour relevant to people with diabetes, and one on a behaviour relevant to HCPs.

Following guidelines from the James Lind Alliance (Partridge & Scadding, 2004), a group of 24 participants, including 6 people with diabetes, 2 policy makers, 13 diabetes HCPs, 2 researchers and 1 psychologist took part in a nominal group technique consensus process. This nominal group technique (or expert panel) had been utilised in previous research to bring patient and HCPs together to prioritise treatment uncertainties for research in the area of cancer care and diabetes, (Crowe, Fenton, Hall, Cowan, & Chalmers, 2015; Gadsby et al., 2012) and has since been utilised across other areas to develop research priorities (Hennessy et al., 2018).

The goal of this process was for stakeholders to identify, and achieve consensus on, the most important target behaviours for research, that are relevant to people with diabetes and diabetes HCPs within three areas: managing T1DM diabetes, managing T2DM and preventing T2DM. The process was completed through an online survey in which participants generated lists of important target behaviours in these three areas, and a subsequent research prioritisation meeting. Within the prioritisation meeting, participants anonymously ranked target behaviours in two rounds. Between ranking rounds, a group discussion took place in which participants could voice opinions regarding priority behaviours (the full process can be found in Appendix I: Mc Sharry et

al. (2016)). This process of private ranking is a key feature of the nominal group technique, as it ensures that all participants have an equal voice and reduces social pressure to conform (Partridge & Scadding, 2004).

The highest ranked behaviour for people with T1DM was to ‘take insulin as required’, and for people with T2DM ‘attend and engage with structured education programmes’. For both T1DM and T2DM, ‘Engaging in collaborative goal-setting with patients’ was ranked as the priority behaviour for HCPs. Diabetes stakeholders felt that collaborative goal-setting was a HCP priority behaviour for diabetes research in Ireland, and was considered to be a valuable behaviour to target in future intervention development. This stakeholder perspective was strengthened by further exploration of the diabetes literature focussing on goal-setting. Significant gaps in the knowledge base were identified within this area, which will be outlined in the following sections. Guided by this collaboratively set priority behaviour and previous literature, the purpose of this research was to create a better understanding of goal-setting behaviours in a diabetes context.

Goal-setting was chosen as a priority HCP behaviour for research in both T1DM and T2DM. When creating a clearer understanding of goal-setting behaviours in a diabetes context, drawing information from research conducted in the areas of both T1DM and T1DM can be beneficial. However, while many similarities exist between self-management behaviours and diabetes support strategies for T1DM and T2DM, there are also substantial differences in the management of both illnesses (Ahlqvist et al., 2018). Limited research has been conducted in exploring the effects and implementation of goal-setting strategies in a diabetes context. In addition, research focussing on goal-setting in the context of diabetes tends to focus on T2DM solely (Donnell et al., 2018; Miller & Bauman, 2014). Glycaemic control tends to be

significantly lower in people with T1DM compared to people with T2DM (NHS, 2014). Furthermore, HCP support is thought to play a crucial role in the management of T1DM due to the typical early onset of the illness, and the complexity of its self-management regimen (Daneman, 2006; Karlsen et al., 2012). Therefore, while this research will intend to create a clearer understanding of goal-setting in a diabetes context by drawing knowledge from research focussing on T1DM and T2DM, its primary focus will be to explore the implementation of goal-setting strategies within T1DM.

1.6 Goal-setting

The concept of goals and goal-setting plays a prominent role in several psychological and behaviour change theories (Austin & Vancouver, 1996). Goals are a broad construct, because goals can be seen as long term aspirations or the end points of short term actions (Vohs & Baumeister, 2016). Within behaviour science, behaviour is often thought of in terms of goals, because goals, or intentions to perform a behaviour, are frequently theorised to be the most important predictor of the respective behaviour (Sniehotta, 2009).

1.6.1 Self-regulation and the Common Sense Model.

Goals have been defined in various ways, but are often described as the objects or aims of an action (Locke & Latham, 1990; Locke & Latham, 2002). By definition, goals are future-oriented as they relate to how people think of their unrealized capabilities and their desired achievements (Austin & Vancouver, 1996). Goals are central to self-regulation models of behaviour such as Leventhal's self-regulation theory, also known as the Common-Sense Model (Leventhal & Brisette, 2003). This model has been increasingly used to identify how several areas of health beliefs are associated with treatment adherence in chronic illnesses (Horne & Weinman, 2002).

Self-regulation is often construed as a systematic process that involves conscious efforts to modulate thoughts, emotions, and behaviours in order to achieve goals or desirable outcomes (Cameron & Leventhal, 2003). According to the Common-Sense Model, adaptation to a chronic illness such as diabetes is a dynamic self-regulation process (Diefenbach & Leventhal, 1996; Leventhal & Brisette, 2003). When faced with a health threat such as diabetes, people develop dynamic and interactive cognitive and emotional representations of their experience in order to make sense of their illness (Leventhal & Brisette, 2003). These common-sense beliefs, known as illness representations, are composed of five components: Identity, referring to the label or name given to the condition and the symptoms that 'appear' to go with it; cause, which refers to the perceived cause of the condition; time-line, which centres on patients' belief about how long the condition might last; consequences, referring to disease effects and impact; and curability or controllability, which focusses on the beliefs about whether a condition can be cured or kept under control and the degree to which someone is able to control this. The illness representations that people form are then used to create a framework for the selection of short- and long-term goals and plans and the selection of certain coping procedures to manage symptoms and regulate negative emotions (Diefenbach & Leventhal, 1996; Hale, Treharne, & Kitas, 2007; Leventhal & Brisette, 2003). Illness representations are dynamic and open to modification based on a self-regulatory evaluation process where the success of selected coping procedures in achieving goals is evaluated (Cameron & Leventhal, 2003). People's illness beliefs or representations influence the goals people set for themselves and their coping behaviours, which influence health outcomes (Leventhal & Brisette, 2003). Self-regulation models such as the Common-Sense Model see individuals as agents that are continuously acting in a conscious or unconscious manner to achieve goals (Diefenbach & Leventhal, 1996).

The Common-Sense Model has repeatedly been shown to predict self-management behaviour in diabetes (Barnes, Moss-Morris, & Kaufusi, 2004). Illness representations are suggested to be adaptable and strategies to understand and change these representations, such as education, can improve self-management behaviours, and health outcomes (Harvey & Lawson, 2009; McAndrew et al., 2008). Furthermore, advising people on how, when and where to respond through goal-setting strategies and developing action-plans can progress behaviour change efforts in diabetes (de Ridder, Theunissen, & van Dulmen, 2007; Leventhal, Phillips, & Burns, 2016; McAndrew et al., 2008).

1.6.2 Goal-setting and determinants of change.

The goals that people strive to achieve can differ in abstraction, ranging from very abstract goals such as ‘being a healthy person’, down to very specific goals such as ‘cycling to work instead of taking a car’. Furthermore, goals can differ in terms of focus, with some goals being construed as approaching a desired end point, and others avoiding an unfavourable end point (Carver & Scheier, 1982). Because many theoretical models are underpinned by the idea that goals influence behaviour (Austin & Vancouver, 1996), active goal-setting to facilitate behaviour change has become a widely implemented strategy within health research (Mann, De Ridder, & Fujita, 2013).

Goal-setting strategies involve determining which goals one wants to pursue and what criteria someone will use for determining a successful outcome. Depending on situational and personal factors, this process of setting goals can be fairly effortless, or involve serious consideration and cognitive resources (Vohs & Baumeister, 2016). Goal-setting can be done on an individual level or on a group level, and can done privately or guided and supported by others such as HCPs (Locke & Latham, 2002). Goal-striving refers to the process of trying to achieve goals and the planning and

executing actions that are associated with goal attainment and protecting goals from disruption (Mann et al., 2013; Vohs & Baumeister, 2016). Setting goals can facilitate behaviour change through motivating our actions, regulating our behaviour, and are used as the standard to judge behavioural performance (Latham, 2003; Latham & Locke, 1991). However, simply setting goals does not always lead to behaviour change and goal achievement (Schwarzer & Luszczynska, 2008; Sniehotta, Scholz, & Schwarzer, 2005). There are several theoretical determinants that are associated with more successful goal-striving and achievement.

One of the most prominent theories addressing determinants associated with the success of goal-setting strategies is ‘goal-setting theory’ (Locke & Latham, 1990; Locke & Latham, 2002). Originally developed within the context of organisational psychology (Locke, & Latham, 2002), goal-setting theory has been used to explain and change behaviour across several domains including health (Strecher et al., 1995). This theory highlights a number of variables that can moderate the effects of goal-setting on achieving an outcome, from the nature of the goals, to personal attributes and the amount of feedback available (Latham, 2003; Locke & Latham, 1990; Locke & Latham, 2002). Goal-setting theory states that setting conscious, specific, non-complex goals, that are challenging yet achievable, tends to lead to better performance than unchallenging, easy, or unclear goals (Locke & Latham, 2002). Several reviews have shown that specific goals, preferably set in terms of behaviour as opposed to outcomes, such as “walk three times a week for 20 minutes”, tend to be more effective than general intentions or vague goals (e.g., “I will be healthier”) or “do your best” goals (e.g., “I do my best to exercise more”) (Kleingeld, van Mierlo, & Arends, 2011; Tubbs, 1986; Wood, Mento, & Locke, 1987). Furthermore, goals that are low in task complexity (i.e., lower number of acts and decisions required to reach the goal) have

been associated with higher levels of goal-achievement (Wood et al., 1987). Goals should be sufficiently challenging and difficult to promote behaviour change. However the goal needs to remain attainable (Locke & Latham, 2002). Meta-analytic evidence, showed medium to large effects of setting sufficiently difficult goals on goal-attainment (Mento, Steel, & Karren, 1987).

In line with self-determination theory, it is thought that self-set goals and collaboratively set goals tend to encourage more behavioural change and action than externally set, or predetermined goals (Heisler, Bouknight, Hayward, Smith, & Kerr, 2002; Heisler & Piette, 2005; Ryan & Deci, 2000). In other words, the more a person is involved in the development of one's goals, the more likely it is that goal achievement will occur (Ryan & Deci, 2000, 2000). Self-determination theory (Ryan & Deci, 2000, 2000) emphasises the distinction between intrinsic motivation, referring to motivation to take action due to its inherent satisfaction, and extrinsic motivation, referring to motivation as a result of more personally-detached outcomes such as external reward or punishment. Higher levels of intrinsic motivation cause increased autonomy in people and often lead to more action. Self- or collaboratively-set goals are often more intrinsically motivated and therefore have a tendency to lead to more effort and longer lasting motivation (Heisler et al., 2002; Heisler & Piette, 2005; Ryan & Deci, 2000). In the case of chronic illness self-management, self-determination theory suggests that maintaining behaviours over time requires patients to internalize beliefs and skills for change. By maximizing patient's experiences of autonomy in health-care settings, through strategies such as collaborative goal-setting, the regulation of self-management behaviours is more likely to be internalized, and behaviour change has a better chance of being maintained (Ryan, Patrick, Deci, & Williams, 2008; Williams et al., 1998).

According to Locke and Latham (2002), the attainment and achievement of goals can be enhanced significantly by incorporating feedback strategies (i.e., data about recorded behaviour or evaluating performance). Furthermore, combining feedback with rewards (i.e., incentives that are explicitly linked to specific behavioural achievements), can have additional benefits for goal-attainment.

1.6.2.1 Action-planning and SMART goals.

Planning strategies such as developing specific action-plans to assist goal-striving have been suggested to increase the likelihood of goal-attainment (Latham & Locke, 1991; Sniehotta, 2009). Action-planning is commonly known as a process of linking goal-directed behaviours to specific environmental prompts by specifying when, where, and how someone should act. Models such as the 'self-regulation model of the Health Action Process Approach' (HAPA) (Schwarzer & Luszczynska, 2008) have highlighted that people go through stages of behaviour change. The Health Action Process Approach specifies that in the process of changing behaviour, individuals go through a goal-setting phase (motivation) and a goal-pursuit phase (volition). After goals or intentions have been formed and people have decided to change their behaviour, people can still remain inactive. The Health Action Process Approach highlights that planning skills are a key tool to transform abstract goals into action.

Specifying a set of more specific goals, and developing action-plans containing short-term goals and action sequences have been shown to increase the likelihood of behaviour change (Sniehotta, Scholz, et al., 2005; Sniehotta, Schwarzer, Scholz, & Schüz, 2005). In fact, Latham and Locke (1991) highlight a process known as the 'high-performance cycle' (p. 233) in which they highlight that combining feedback, task strategies such as action-planning, and rewards associated with one's goals will likely lead to higher levels of success than setting a goal alone. Additionally, action planning

has been linked to the formation of habits as research has suggested that engaging in these planning strategies enables people to use environmental cues to achieve a goal and ideally use less self-regulatory resources in their goal-striving (Gollwitzer, 1999; Sniehotta, Schwarzer, et al., 2005).

Related to action-planning strategies, and guided by goal-setting theory, is the utilisation of the SMART-goal acronym (Abraham & Michie, 2008; Bovend'Eerdt, Botell, & Wade, 2009). There are a number of variations of this acronym, which proposes that goals should be formulated in accordance with five main principles. Goals should be: Specific, written and describe precisely what is being pursued; Measurable, one should be able to measure when a goal has been accomplished; Achievable, goals should be challenging, but remain attainable; Realistic/ Relevant, goals should be possible to accomplish and should be relevant to the person concerned; and Timely, the goal should contain an achievement deadline (Abraham & Michie, 2008; Bovend'Eerdt et al., 2009; Lawlor, 2012). Using the SMART acronym when setting goals has become a widely implemented technique in behaviour change research (Abraham & Michie, 2008; Sniehotta, 2009).

1.6.2.2 Self-efficacy.

Models such as the Health Action Process Approach and goal-setting theory highlight that self-efficacy significantly influences goal-setting practices and goal achievement. This is well described within Social Cognitive Theory (Bandura, 1986), which recognises that self-efficacy, an individual’s belief that one is capable of executing a specific behaviour in a particular situation (Bandura, 1977), is seen as lying at the core of successful behaviour change. Higher levels of self-efficacy are thought to positively affect behavioural change and goal-achievement (Locke & Latham, 2002; Strecher et al., 1995). Goal-setting practices can both influence and be influenced by

self-efficacy (Locke & Latham, 2002). People with higher self-efficacy set more ambitious goals, and tend to be more motivated than people with lower self-efficacy (Bandura, 1977; Locke, Frederick, Lee, & Bobko, 1984; Zimmerman, 2000). Furthermore, goal-achievement causes further increases in self-efficacy. However, if people fail to meet their goals, self-efficacy tends to drop, often leading to goal desertion. In other words, achievement generates further achievements while failure leads to more failure (Locke & Latham, 2002). Therefore, setting specific, noncomplex, and challenging yet still attainable goals is important to facilitate goal-achievement and increase self-efficacy.

1.6.2.3 Optimal application of goal-setting.

Guided by theoretical components, optimal application of goal-setting practices in behaviour change should therefore encourage people to set goals which are specific, noncomplex, and challenging (without being unattainable), hereby increasing the likelihood of goal-achievement and increasing self-efficacy (Bandura, 1986; Locke & Latham, 2002; Ryan & Deci, 2000). Furthermore, developing action-plans, providing feedback on goal-progress and attainment, and possibly rewarding goal-achievement is thought to be beneficial for the process of behaviour change.

The overall effectiveness and the implementation of goal-setting techniques on behaviour change has been assessed in a recent systematic review and meta-analysis (Epton, Currie, & Armitage, 2017). This review aimed to assess the effects of goal-setting focused interventions on behaviour change, and under what circumstances and for whom goal-setting techniques worked best. Based on the data of 141 randomised controlled goal-setting interventions, aimed at changing various behaviours, the meta-analysis indicated that participants in goal-setting conditions of interventions showed greater behaviour change across behaviours compared to participants in control

conditions. Furthermore, moderator analyses indicated that goal-setting strategies were particularly effective if goals were: sufficiently difficult; set publicly as opposed to individually or computerised and framed as group goals (Epton et al., 2017).

1.7 Goal-setting in diabetes self-management

Goal-setting techniques are widely implemented within the area of diabetes self-management (Beck et al., 2017; Funnell et al., 2009; Haas et al., 2012; Presseau et al., 2015). Strategies that enable people with diabetes to make decisions about health and behavioural goals are considered to have a positive impact on diabetes-self management (Funnell & Anderson, 2004). Therefore, goal-setting and action-planning strategies are increasingly included in guidelines for diabetes support strategies and have become essential parts of many primary care improvement schemes (Beck et al., 2017; Chin et al., 2007; Haas et al., 2012).

1.7.1 Goal-setting in HCP support.

The Chronic Care Model, includes goal-setting and action-planning as a central component in diabetes support (Bodenheimer, Lorig, et al., 2002; Bodenheimer, Wagner, et al., 2002). Self-management plans are encouraged to fit patients' own goals, priorities, resources, culture, and lifestyle (American Diabetes Association, 2014; Beck et al., 2017; Funnell & Anderson, 2004; Funnell et al., 2007). Therefore, HCPs are typically advised to engage in collaborative goal-setting strategies with people with diabetes (Battersby et al., 2010; Funnell & Anderson, 2004).

Collaborative goal-setting can be described as a process by which HCPs and people with diabetes agree on diabetes-related goals. These goals can be quite general (reduce HbA1C or exercise more) or quite specific (walking for 15 minutes four times a week) (Taylor et al., 2014). Specific goals are often accompanied by action-plans,

which involve HCPs and people with diabetes agreeing on a concrete course of action to move an individual towards a diabetes goal (Sniehotta, Schwarzer, et al., 2005; Von Korff, Gruman, Schaefer, Curry, & Wagner, 1997).

In line with self-determination theory (Ryan & Deci, 2000) and goal-setting theory (Locke & Latham, 2002), research shows that when HCPs engage in collaborative goal-setting with people with diabetes, people show higher levels of autonomy motivation and tend to achieve better diabetes control (Heisler et al., 2002; Heisler & Piette, 2005). Collaborative goal-setting is suggested to enable people with diabetes to be more actively involved their care, resulting in higher levels of empowerment (Anderson et al., 1995; De Sutter et al., 2013). Furthermore, it is suggested to guide the creation of treatment plans that are more likely to be attained (Golin, DiMatteo, & Gelberg, 1996; Heisler et al., 2002). Additionally, collaborative goal-setting is associated with increasing patients' self-efficacy level and motivation (Estabrooks et al., 2005; Marks & Allegrante, 2005). This was supported by Raaijmakers et al. (2014) when conducting a study in which they measured the level of autonomy support people with diabetes received from HCPs. Higher levels of autonomy support meant a more person-centred approach and more collaborative goal-setting. Consistent with previous studies, they found that people who perceived more autonomy support had higher levels of intrinsic motivation and significantly better self-management skills (Williams, Lynch, & Glasgow, 2007). Lafata et al. (2013) found that people with diabetes who reported higher levels of engagement in collaborative goal-setting, were more likely to have higher perceived competency in managing their diabetes as well as having heightened levels of trust in their HCPs. Given these findings, it seems advisable that diabetes care takes place in a collaborative manner,

negotiating goals and action-plans with people with diabetes rather than determining goals for them (Bodenheimer & Handley, 2009).

1.7.1.1 Goal-setting in HCP support: Issues of implementation

Within the research prioritisation exercise (Mc Sharry et al., 2016), stakeholders felt that more research is warranted surrounding the implementation of goal-setting in diabetes care, and possibly around promoting this behaviour in HCPs. Stakeholders concerns are supported by research suggesting that goal-setting and follow-up support activities are some of the least reported activities in diabetes care (Duke, Colagiuri, & Colagiuri, 2009; Glasgow, Whitesides, Nelson, & King, 2005). In an Irish context, a recent questionnaire based study by Darker, Whiston, and O'Shea (2015) revealed that only a minority of people with diabetes reported being asked about their ideas or goals when making a treatment plan with HCPs. Several studies have shown that HCPs are reluctant to engage in goal-setting practices with patients and often don't engage with these collaborative care approaches (Corser, Holmes-Rovner, Lein, & Gossain, 2007; Pill, Stott, Rollnick, & Rees, 1998). MacGregor et al. (2006) found that HCPs viewed goal-setting as time consuming, and adding time-consuming activities to patient visits was suggested to be a barrier for implementation. Furthermore, people with diabetes have been reported to experience a lack of empathy from HCPs, and experience differences in views on diabetes management goals during clinic appointments (Campbell et al., 2003; Ho et al., 2010). It appears that is not always understood how collaborative goal-setting can be most feasibly, effectively, and sustainably integrated into busy healthcare practice settings (Bodenheimer & Handley, 2009).

1.7.2 Goal-setting in Diabetes Self-Management Education.

One area of diabetes support where goal-setting strategies are increasingly reported and implemented in a structured manner is Diabetes Self-Management

Education (DSME; Grant et al., 2013). Haas et al. (2013) describe DSME as the continuous process of facilitating knowledge, skill, and abilities necessary for diabetes self-care. The overall objectives of DSME are to support informed decision making, self-care behaviours, problem solving, and active collaboration with the healthcare team and additionally to improve clinical outcomes, health status, and quality of life in people with diabetes. DSME is a critical element of diabetes support (Ogurtsova et al., 2017) and is recommended in national and international guidelines to be offered to all people with diabetes (American Diabetes Association, 2014; Healthy Ireland, 2017), as it is considered necessary in order to prevent or delay diabetes complications (Haas et al., 2013).

While DSME can take place on an individual level or a group level, and the mode of delivery can vary from written materials to standardised face-to-face courses, there is a rise in structured DSME programmes delivered in a group format (Chrvala, Sherr, & Lipman, 2016). These courses can be an efficient way to change people's illness representations and teach appropriate self-management behaviours, hereby empowering people with diabetes to live healthily and manage their diabetes better (American Diabetes Association, 2014; DAFNE study group, 2002; Funnell & Anderson, 2004). Structured DSME programmes tend to follow written curriculums and manuals that reflect current evidence and practice guidelines, and are typically delivered by trained educators (Funnell et al., 2009). Therefore, in addition to providing continuous self-management support in clinic appointments, HCPs are often involved in the delivery of these DSME programmes.

DSME programmes have been evolving significantly in recent years and are increasingly implementing psychological theory and behavioural constructs (Davies et al., 2008). Congruent with the advances in diabetes care, increasing emphases are put on

person-centred and collaborative approaches to education (Funnell et al., 2007). As part of this movement, DMSE has implemented empowerment-based components and behaviour change strategies such as goal-setting and action-planning (Funnell et al., 2007). This is a step forward from historical approaches in which the principal focus to changing behaviour was based on information-provision (Marteau, Hollands, & Kelly, 2015). Guidelines for developing DSME highlight the need for including strategies as action-oriented behaviour change goal-setting and action-planning and recommend these strategies as suitable ways to individualise diabetes education. Furthermore, implementing person-centred, experience-based delivery methods are recommended that go beyond knowledge acquisition and are effective for supporting informed decision making and behaviour change while addressing psychosocial concerns (Beck et al., 2017; Haas et al., 2013). Goal-setting and planning strategies are seen as important efforts in enhancing patient autonomy, and automating future responses to internal and external ques (Hollands, Marteau, & Fletcher, 2016), and could therefore promote long-term behaviour change in DSME programmes, if implemented accurately (Epton et al., 2017; Latham, 2003). Consequently, goal-setting has been identified as one of the four central components present across structured diabetes education programmes (Grant et al., 2013). Furthermore a large scale questionnaire based study by Malemute, Shultz, Ballejos, Butkus, and Early (2011) revealed that the majority of DSME educators report that more than 75% of their patients set goals for diabetes control during DSME programmes.

1.7.2.1 DSME Effectiveness.

In a systematic review of T2DM DSME interventions, Norris et al. (2002) reported that overall, DSME leads to immediate improvements in Hba1C levels. A recent systematic review (Chrvala et al., 2016) supported these findings and reported

that the extent of Hba1C reductions in participants exposed to DSME surpassed that of usual care by more than 0.5%. This review additionally suggested that DSME interventions with more than ten contact hours were more often associated with more significant decreases in HbA1C. However, both systematic reviews concluded that while DSME improves HbA1C levels in the short term, its long-term effects are less promising. Norris et al. (2002) found that clinical benefits declined a few months after the interventions were finished, suggesting that long term behaviour change is difficult to achieve.

1.7.2.2 Dose Adjustment for Normal Eating.

The 'Dose Adjustment for Normal Eating' (DAFNE) programme (DAFNE study group, 2002) is a good example of a DSME programme that has been widely implemented in practice and has become part of routine diabetes care within Ireland, the United Kingdom, Australia, New Zealand and several other countries (DAFNE U.K., 2017). DAFNE is a five day DSME programme that covers all aspects of living with T1DM. The programme is predominantly delivered by trained nurses and dieticians and follows a set curriculum outlined in an intervention manual and emphasises the key skill of matching insulin to estimated carbohydrate intake to improve both HbA1c and dietary flexibility, and thereby quality of life (DAFNE study group, 2002).

Congruent with guidelines (Beck et al., 2017; Haas et al., 2013), DAFNE has embraced empowerment-based components and behaviour change strategies such as goal-setting and action-planning (Oliver & Thompson, 2009). Studies have shown that DAFNE graduates tend to have greater diabetes knowledge and show long-term improvements in quality of life (Cooke, Bond, Lawton, Rankin, Heller, Clark, & Speight, 2013; Dinneen et al., 2009; Speight et al., 2010). However, in line with findings from research assessing T2DM DSME effectiveness, DAFNE's long-term

benefits for average blood-glucose levels (HbA1c) tend to be more modest (Gunn & Mansell, 2012; Speight et al., 2010). Longitudinal research reveals that initial improvements in HbA1c, while statistically significant, tend to decrease over subsequent years (Cooke, Bond, Lawton, Rankin, Heller, Clark, & Speight, 2013; Gunn & Mansell, 2012; Speight et al., 2010). It seems that even though DAFNE has become an established programme within diabetes care, it does not always help participants to sufficiently incorporate key self-management behaviours into their lives on a long-term basis. Speight et al. (2010) therefore highlighted the need to modify DAFNE and pay special attention to components likely to contribute to successful behaviour change and maintenance.

1.7.2.3 Goal-setting in DSME and DAFNE: Issues of implementation.

DSME programmes such as DAFNE are targeting self-management behaviour change by structurally implementing behaviour change strategies such as goal-setting. However, DSME's impact on behaviour change is often limited (Norris et al., 2002). As goal-setting is widely-recommended for promoting behaviour change, exploring goal-setting behaviours within a DSME context is vital (Latham, 2003). However, limited research has explored how goal-setting strategies are implemented within DSME and how these strategies effect diabetes related outcomes (Sprague, Shultz, & Branen, 2006). Furthermore, little is known about how these strategies are operationalised in practice and whether these goal-setting components are implemented correctly and as originally intended by the programme developers (Schinckus, Van den Broucke, Housiaux, & Consortium, 2014).

An issue in establishing DSME programme effectiveness and exploring the advantage of goal-setting strategies in this context is the lack of focus on implementation fidelity in this area. Implementation fidelity has been described as the

extent to which an intervention, programme or treatment is implemented as originally intended (Bellg et al., 2004). A large body of evidence shows that face-to-face interventions are often not delivered as specified in their intervention manuals (Bellg et al., 2004; Campbell et al., 2000). This kind of variation in intervention delivery could affect outcomes and treatment effectiveness (Bellg et al., 2004), with high levels of implementation fidelity often being related with more positive outcomes (Hasson, Blomberg, & Dunér, 2012; Keith, Hopp, Subramanian, Wiitala, & Lowery, 2010). Addressing implementation fidelity within intervention research is becoming increasingly important; both the extension of the CONSORT statement for non-pharmacological treatments (Boutron, Moher, Altman, Schulz, & Ravaud, 2008) and the Medical Research Council Guidance on intervention development and evaluation (Craig & Petticrew, 2013) emphasise the importance of monitoring and reporting the extent to which interventions are delivered as planned.

Although the importance of examining implementation fidelity is widely recognised, research shows that it is often not assessed within DSME (Bellg et al., 2004; Schinckus et al., 2014). This was highlighted in a recent systematic review by Schinckus et al. (2014), which set out to clarify how implementation fidelity is currently operationalized and assessed within DSME programmes. Schinckus et al. (2014) found that very few studies addressed the issue of implementation fidelity, and when it was mentioned, the information provided was often incomplete. It seems that while scientific movements are pushing towards higher levels of implementation fidelity measures, it is still a rarity that fidelity is assessed within interventions or education programmes delivered in practice. To adequately assess the quality and effectiveness of goal-setting and other techniques in DSME, more research is needed addressing implementation fidelity of these programmes.

While goal-setting is commonly part of DSME curriculums (Grant et al., 2013), and many educators report to engage in person-centred practices such as goal-setting, patterns of practice reveal that diabetes educators significantly vary in how they apply education practices (Malemute et al., 2011). Arguably, a level of expertise around theoretical moderators of behaviour change principles is required when delivering components such as goal-setting (Epton et al., 2017; Kok et al., 2016), yet limited research exists surrounding DSME educators' understanding of these principles (Bodenheimer & Handley, 2009). Furthermore, while goal-setting and action-planning strategies are being increasingly implemented and recommended (Haas et al., 2013), we know very little about how DSME educators experience the implementation and delivery of these strategies (Snow, Sandall, & Humphrey, 2014). Engaging in person-centred goal-setting could arguably be challenging for DSME educators and HCPs, as it requires a paradigm shift away from the traditional HCP-led model of diagnosis and treatment, to a more collaborative model in which people set personally-motivated goals (De Sutter et al., 2013). More research focussing on the implementation of goal-setting in DSME and exploring HCPs' attitudes surrounding this implementation could significantly advance the understanding of HCPs' goal-setting behaviours in a diabetes care setting. Furthermore, possible barriers and facilitators to HCPs' application of goal-setting strategies in routine diabetes care could be identified.

1.7.2.4 Specifying goal-setting content: Behaviour Change Techniques.

An additional issue in exploring the implementation of goal-setting strategies within the context of DSME programmes and diabetes support is the lack of clarity surrounding the description of implemented goal-setting content. Complex interventions, like DAFNE, consist of a number of components which operate both independently and inter-dependently (MRC, 2000). To improve or further implement a

DSME programme or an intervention, it is important to establish which components are the active ingredients and how they are exerting their effects (Craig et al., 2013). Specifying the components of an intervention like DAFNE and verifying that they are delivered and delivered well is vital for rigorous research practice (Santacroce, Maccarelli, & Grey, 2004).

Within the field of behavioural science, recent movements propose that behaviour change intervention content should be specified in terms of Behaviour Change Techniques (BCTs) to improve clarity around the mechanisms by which behaviour is suggested to change (Abraham & Michie, 2008; Craig & Petticrew, 2013; Michie et al., 2013). Michie et al. (2013) furthered this movement by developing a comprehensive taxonomy, or list, of BCTs. BCTs can be described as the "observable, replicable, and irreducible components of interventions that are designed to change or redirect causal processes that regulate behaviour" (Michie et al., 2013, p. 82), and are proposed to be the smallest active component of an intervention that can bring about change (Michie et al., 2013). The taxonomy consists of 93 BCTs clustered into 16 groups. Each BCT has a clear label and description, and holds specified criteria for its usage or operationalisation. Taxonomies such as the Behaviour Change Technique Taxonomy Version 1 (BCTTv1) provide a common language and definitions for describing the active content of complex behaviour change interventions (Lorencatto, West, Christopherson, & Michie, 2013; Michie, Abraham, Whittington, McAteer, & Gupta, 2009; Michie et al., 2013).

According to the BCTTv1 (Michie et al., 2013), 'goals and planning' is one of 16 broad clusters that contain a total of nine specific BCTs. BCTs such as 'goal-setting, behaviour' and 'goal-setting, outcomes' represent different types of goal-setting, with 'goal-setting, behaviour' described as 'setting or agreeing on a goal in terms of

behaviour to be achieved' and 'goal-setting, outcome' defined as 'setting a goal in terms of a positive outcome of wanted behaviour' (Michie et al., 2013, p. 92). Furthermore, BCTs such as 'action-planning' and 'problem-solving' represent strategies that often accompany goal-setting by outlining specific plans to reach goals and identifying barriers which could arise in the process of goal-attainment. Additionally, BCTs from the 'feedback and monitoring' cluster, such as feedback provision on behaviour represent strategies that are thought to mediate the effectiveness of goal-setting strategies (Locke & Latham, 2002; Strecher et al., 1995). While other strategies exist for describing intervention content within the field of behaviour change (Kok et al., 2016), the BCTTv1 describes the different types of goal-setting most clearly (McEwan et al., 2016; Michie et al., 2013).

1.7.3 Goal-setting BCTs in self-management behaviour change interventions.

In addition to routine HCP support and DSME programmes, behaviour change interventions targeting diabetes outcomes, are increasingly implementing goal-setting BCTs. A recent systematic review (Presseau et al., 2015) coded the BCTs implemented within a wide range of behaviour change interventions aimed at improving diabetic outcomes. The included interventions were both targeted at HCPs and people with diabetes. The review found that 'goal-setting (behaviour)' was one of the most commonly implemented BCTs in interventions targeting both providers, and people with diabetes.

While goal-setting has been widely implemented within behaviour change interventions, the evidence around its effectiveness as an intervention strategy to promote diabetes self-management is lacking clarity. A recent systematic review of interventions, aimed at increasing physical activity in adults with Type 2 diabetes,

identified which BCTs were utilized within the interventions and which BCTs were associated with improvements in HbA1C (Avery et al., 2012). The analyses suggested that ‘goal-setting and planning BCTs’ such as ‘review of behavioural goals’ and ‘goal-setting, behaviour’ were associated with improvements in HbA1c. While these findings are encouraging for the effectiveness of goal-setting techniques in improving diabetic outcomes, this review included only interventions using physical activity as a strategy for diabetes self-management. Physical activity is a viable self-management option for people with Type 2 diabetes, however it is not the only self-management option and other behaviours could be equally essential (Ahola & Groop, 2013). Furthermore, these BCTs were incorporated within multi-component complex interventions. It is therefore unclear if the effects were moderated through the use of other BCTs, and how effective these goal-setting techniques would be if they were implemented as the primary intervention strategy of an intervention.

Utilising goal-setting as the primary intervention strategy has been shown to be an effective method of change for behaviours such as physical activity across a range of populations (McEwan et al., 2016). However, limited explorations have been done to assess the effectiveness of goal-setting focussed interventions targeting people with diabetes and diabetes management. A previous review by Miller and Bauman (2014) attempted to address this gap by giving an overview of interventions that had incorporated goal-setting as their primary strategy for improving self-management behaviours and health outcomes in people with T2DM. While this review provided some information on health and behavioural outcomes following goal-setting focussed interventions, assessing intervention effectiveness was not the primary focus of this review. Therefore, it was largely descriptive and provided little information on the overall effectiveness of goal-setting interventions in a diabetes context. Furthermore,

this review provided no information on the active content of these interventions in terms of incorporated BCTs, nor were interventions targeting T1DM included. Miller and Bauman (2014) therefore highlighted that more systematic research is needed to determine the effectiveness of goal-setting in the context of behaviour change interventions, and the conditions and behaviours for which goal-setting is most effective.

1.8 Rationale for the current research

In a research prioritisation exercise engaging a range of key stakeholders, ‘collaborative goal-setting with patients’ was identified as a priority HCP behaviour for diabetes research in Ireland, and was considered to be a valuable behaviour to target in future intervention development (Mc Sharry et al., 2016). Goal-setting is an important strategy within behaviour change and health research, and the implementation of goal-setting techniques is widely recommended for diabetes self-management support (Funnell et al., 2007). However, currently it is difficult to achieve consensus on the effectiveness of goal-setting techniques in the area of diabetes management, as clarity of evidence is lacking (Miller & Bauman, 2014). To address stakeholder concerns, and to target goal-setting as a possible behaviour in future HCPs intervention development, a clearer understanding of goal-setting’s effectiveness and implementation in a diabetes context is crucial. Therefore, a synthesis of the evidence on goal-setting interventions aimed at improving diabetes outcomes, and assessing their effectiveness, content and conditions for effectiveness is essential. To create a complete overview and clearer understanding of goal-setting behaviours in a diabetes context, drawing information from research conducted in the areas of both T1DM and T2DM is warranted.

In addition to a lack of evidence synthesis around effectiveness, there is limited understanding of how goal-setting strategies are currently implemented within diabetes

care and support. While research shows that goal-setting strategies are insufficiently implemented within diabetes support (Darker et al., 2015), one area of diabetes support in which goal-setting has been identified as a core component, is DSME (Grant et al., 2013). Given the extensive implementation of goal-setting strategies in DSME and the significant role DSME plays in routine diabetes care, DSME was chosen as the context for exploring goal-setting in this thesis. Existing research addressing goal-setting in a diabetes context tends to focus on T2DM as opposed to T1DM (Bodenheimer & Handley, 2009; Donnell et al., 2018; Miller & Bauman, 2014). Creating a better understanding of barriers and facilitators to successful implementation of goal-setting strategies in T1DM diabetes support is necessary. Therefore, investigating how goal-setting is currently implemented within a prominent T1DM DSME programme that is part of routine care, by assessing its active content and delivery characteristics is vital.

Additionally, HCPs are urged to engage in collaborative goal-setting strategies with people with diabetes and to deliver goal-setting and action-planning content in DSME programmes (Funnell et al., 2009; Funnell et al., 2007). However, while HCPs play a crucial role in delivering optimal diabetes care and effective DSME programmes, limited research has explored HCPs' perspectives on operationalising behaviour change strategies such as goal-setting (Snow et al., 2014). Therefore exploring HCPs' insights regarding the implementation of goal-setting strategies is essential to optimise future diabetes care and DSME programmes.

1.9 Aims and objectives

The overall aim of this research was to explore the effectiveness and implementation of goal-setting techniques in diabetes self-management interventions and to explore the implementation of goal-setting techniques in DAFNE, a prominent DSME programme for people with T1DM. To create a clearer understanding of goal-

setting in a diabetes context, knowledge will be drawn from previous research focussing on both T1DM and T2DM. However, the primary focus of this thesis is to explore the implementation of goal-setting strategies within T1DM. The aims and objectives for each study conducted in this research and the corresponding papers are outlined below.

1.9.1 Aims and objectives for individual studies and corresponding papers.

- **Study 1 aim:** Assess the content and effectiveness of goal-setting behavioural change interventions targeting clinical, health, psychosocial or behavioural outcomes in people with diabetes.
    - **Objectives:**
        - To explore the effectiveness of goal-setting behavioural change interventions on clinical, health, psychosocial or behavioural outcomes in people with diabetes.
        - To Identify which "Goals and planning" and "Feedback and monitoring" BCTs (Michie et al., 2013) are most frequently used in these interventions.
        - To identify which BCTs are most effective in improving outcomes.
    - Fredrix, M., McSharry, J., Flannery, C., Dinneen, S., & Byrne, M. (2018). Goal-setting in diabetes self-management: A systematic review and meta-analysis examining content and effectiveness of goal-setting interventions. *Psychology & health*, *33*(8), 955-977. doi: 10.1080/08870446.2018.1432760
- **Study 2 aim:** Explore the content and the fidelity of delivery of the goal-setting component of DAFNE.

- **Objectives:**
  - Identify the active content of DAFNE's goal-setting component in terms of BCTs (Michie et al., 2013).
  - Assess overall fidelity of delivery of the goal-setting sessions, using a checklist of manual-identified BCTs.
  - Assess variation in fidelity according to educator, session type, and specific BCTs.
  - Identify implemented BCTs not specified within the intervention-manual.
- Fredrix, M., Byrne, M., Carr, E., McSharry, J. Goal-setting in DAFNE; A content and fidelity exploration of the goal-setting component of a type 1, diabetes self-management programme. Submitted to: *Health Education Research* (submitted April 2018).

- **Study 3 aim:** Explore educators' perspectives on the implementation of goal-setting strategies, supplemented by action-planning within the DAFNE-programme.
  - **Objectives:**
    - Explore how DAFNE educators experience the delivery and practical application of goal-setting and action-planning components within DAFNE.
    - Explore educators' views on the quality of these components.
    - Explore educators' views on possible improvements to these components.
  - Fredrix, M., Byrne, M., Dinneen, S., McSharry, J. (2018). 'It's an important part, but I am not quite sure that it is working':

educators' perspectives on the implementation of goal-setting within the 'DAFNE' diabetes structured education programme. *Diabetic Medicine, 36*(1), 80-87. doi: 10.1111/dme.13813

1.10 Thesis outline

The methodologies used to conduct these studies are outlined in chapter two. The three studies are included in chapters three, four and five. A general discussion of the findings of the studies, the limitations of the studies, and implications for future research and practice is presented in chapter six.

2. Methodology

2.1 Chapter overview

This chapter will outline the overall design of the PhD project and the justification for this choice of design. The aims and objectives of each study will be discussed and a description of the methods used to address these aims and objectives will be provided. Furthermore, a brief discussion of the background and justification for applying these specific methods will be presented for each study. The ethical considerations that are associated with each study will be addressed at the end of the chapter.

2.2 Aims and objectives of this research

The overall aim of this research was to explore the effectiveness and implementation of goal-setting techniques in diabetes self-management interventions and to explore the implementation of goal-setting techniques in DAFNE, a prominent Diabetes Self-Management Education (DSME) programme for people with T1DM. Quantitative and qualitative methods were used to develop the evidence by integrating data from existing literature and observational research with perspectives of key stakeholders in relation to the topic of goal-setting in diabetes care.

2.3 Overview of study design and justification

Diabetes stakeholders selected ‘collaborative goal-setting with patients’ as a HCP priority behaviour for diabetes research in Ireland, and considered this to be a valuable behaviour to target in future intervention development (Mc Sharry et al., 2016). The UK Medical Research Council (MRC) framework (Campbell et al., 2000; Craig et al., 2008, 2013) provides guidance for developing and implementing complex health interventions. This framework highlights that health behaviour change research is

often limited by an inadequate understanding of the mechanisms of change that underpin effective interventions, and a lack of awareness of anticipated issues related to the local contexts and implementation of interventions (Craig et al., 2013; Rowlands, Sims, & Kerry, 2005). Therefore the framework suggest that a vital first part of intervention development is identifying existing evidence and developing a clear understanding of the problem. In line with these recommendations, a combination of quantitative and qualitative methods are applied in this research to create a clearer understanding of HCPs' goal-setting behaviours in a diabetes care setting.

Health services and social science researchers are increasingly utilising qualitative and quantitative methodologies to address research questions in complex settings (Dures, Rumsey, Morris, & Gleeson, 2011; Yardley & Bishop, 2015). Quantitative and qualitative data can be combined for the purpose of completeness in understanding a problem, in order to obtain complementary views, and generating more detail than could be gained from using either method exclusively (McEvoy & Richards, 2006). Quantitative methods can identify patterns and associations that otherwise may not have been uncovered. This may help to tease out new and unexpected causal mechanisms. However, the key strength of qualitative methods is that they are open ended, which allows themes to be identified that could not have been anticipated in advance (Mingers, 2004).

Identifying the evidence base is a crucial first step in behaviour change research and involves identifying what is already known about a topic by detecting similar interventions and establishing the mechanisms of change and methods that have been used to evaluate these interventions (Craig et al., 2008). Evidence synthesis methods, such as systematic reviews and meta-analyses are typically recommended for the identification of this evidence base (Craig et al., 2008, 2013). A systematic review and

meta-analysis was conducted in study 1 to provide valuable insight into the potential effectiveness and active content of goal-setting interventions targeting diabetes outcomes.

While these methods have the potential to offer valuable information regarding the effects and content of existing goal-setting interventions, systematic reviews and meta-analyses provide limited insights in terms of how well interventions are implemented and delivered or received by the target population. Implementation studies and qualitative research with key stakeholders can provide a deeper understanding of these issues (Bellg et al., 2004; Yardley & Bishop, 2015). When exploring possibilities for promoting goal-setting behaviours in HCPs, examining how goal-setting strategies are currently implemented in healthcare and assessing barriers and facilitators to successful implementation of these strategies is vital. Additionally, the MRC framework suggests that optimising and exploring the mechanisms of interventions that have already been implemented, and integrating new knowledge within an existing framework increases the impact of research and enhances the feasibility of change to the healthcare system (Craig et al., 2008, 2013; Craig & Petticrew, 2013). Study 2 and 3 thus focus on exploring the implementation of the goal-setting component of DAFNE, a widely implemented standardised T1DM DSME programme that is part of routine care in Ireland.

Study 2 consists of a content and fidelity exploration of the goal-setting component of DAFNE (DAFNE U.K., 2017). Assessing the active content of this component and comparing this to the active content of goal-setting interventions identified in study 1 and theoretical constructs can provide valuable insights into the current application of goal-setting in an Irish healthcare setting. Furthermore, evaluating characteristics of the delivery of this component (e.g. implementation fidelity,

additional content delivered and session duration) will generate knowledge on how goal-setting techniques are currently implemented in practice (Bellg et al., 2004; Campbell et al., 2000). Consequently, Study 2 utilised a quantitative observational design in which the active content was assessed and delivery characteristics were evaluated of the goal-setting component of DAFNE.

When pursuing changes in health-care or in the behaviour of HCPs, implementation science literature suggests that prior to intervention or policy development, one must carefully consider potential issues surrounding the implementation of these proposed changes (Elmore, 1979). Therefore, exploring HCPs' perspectives on the implementation of goal-setting strategies, and exploring barriers and facilitators to applying these strategies is crucial (Reimers, Wacker, & Koeppl, 1987). Guided by the findings from study 1 and 2, study 3 consists of a qualitative study exploring DAFNE educators' perspectives on the implementation of goal-setting strategies within DAFNE and DSME. A qualitative design will facilitate a deeper understanding of the current implementation of goal-setting in DSME and could provide insights into fidelity levels, as well as guide DSME-programme optimisation. An overview of the studies is visualised in Figure 2.1.

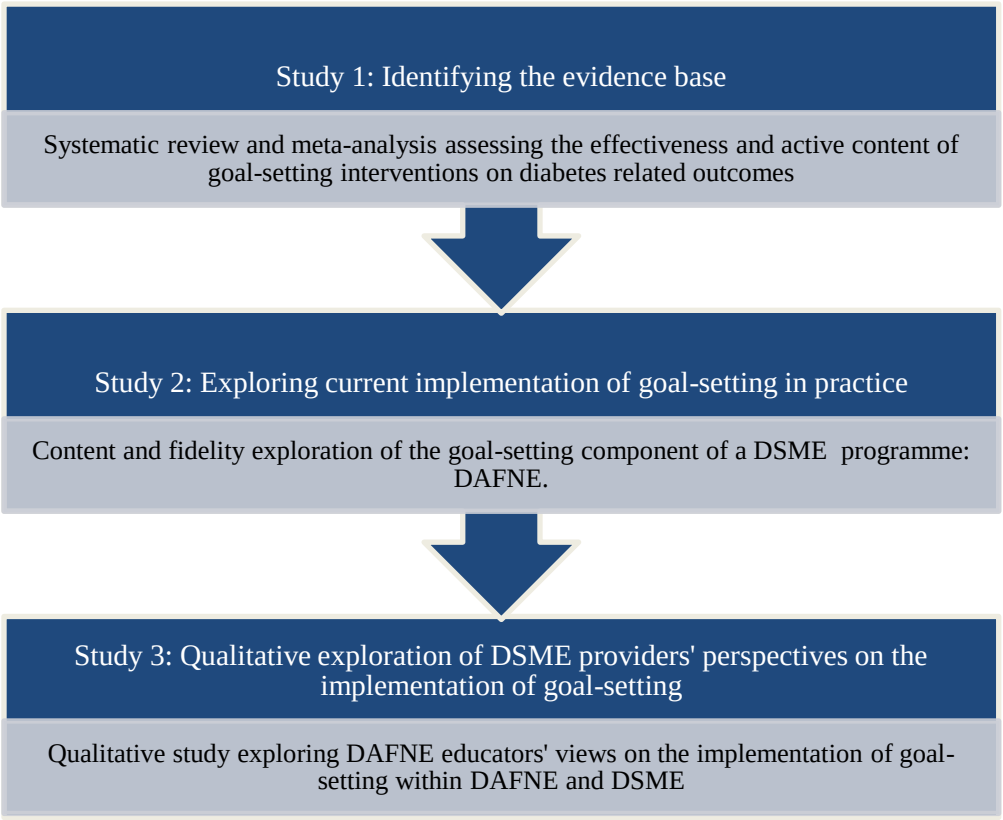

Figure 2.1. Overview of the studies

2.4 Study 1- Identifying the evidence base

2.4.1 Aims and objectives of study 1.

Study 1 aimed to explore the content and effectiveness of goal-setting behavioural change interventions targeting clinical, health, psychosocial or behavioural outcomes in people with diabetes.

- Specific objectives:
    - To assess the effectiveness of goal-setting behavioural change interventions on clinical, health, psychosocial or behavioural outcomes in people with diabetes.

- To Identify which “Goals and planning” and “Feedback and monitoring” BCTs (Michie et al., 2013) are most frequently used in these interventions.
- To identify which BCTs are most effective in improving outcomes.

2.4.2 Approach to study 1.

Goal-setting is a recognized and widely implemented approach to diabetes self-management and self-management education for both T1DM and T2DM within the American Diabetes Association (Franz, Boucher, Green-Pastors, & Powers, 2008). However there is limited evidence available for the effectiveness of goal-setting as an intervention strategy to promote diabetes self-management in these populations (Miller & Bauman, 2014).

Study 1 addressed this research gap by assessing the overall effectiveness of goal-setting focussed interventions targeting a wide range of diabetes outcomes through a systematic review and meta-analysis. Furthermore, this review aimed to specify the active content of these goal-setting interventions in terms of BCTs using the BCTTv1 (Michie et al., 2013).

Specifying the presence or absence of BCTs across studies can provide more information on the different types of goal-setting and feedback strategies that are being implemented. This can inform future intervention development by clarifying which BCTs are most frequently implemented and which mechanisms of change underpin effective interventions.

An explicit and systematic process was utilised in this study to obtain all relevant published literature, to appraise the quality of the existing evidence and to produce a comprehensive and reliable synthesis of the evidence surrounding the

effectiveness of goal-setting interventions targeting diabetes outcomes (Garg, Hackam, & Tonelli, 2008; Higgins & Green, 2011). Meta-analyses combined with narrative syntheses were used to analyse and synthesise the data extracted from the studies included in this systematic review.

This review was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher, Liberati, Tetzlaff, & Altman, 2009). The completed PRISMA checklist is outlined in Appendix II.

A detailed protocol for this review was registered on the International Prospective Register of Systematic Reviews (PROSPERO) database (doi: 10.15124/CRD42015027561).

2.4.3 Procedure.

2.4.3.1 Eligibility Criteria.

2.4.3.1.1 Types of studies.

Eligible study designs included randomised controlled trials (RCTs), non-randomised controlled trials, quasi experimental studies or studies with a pre-post design. Based on a recent review by McEwan et al. (2016) eligible studies were intervention studies utilising goal-setting techniques as the primary intervention strategy to improve health and behavioural outcomes in people with diabetes. The primary focus of the interventions therefore needed to involve setting diabetes self-management goals. Studies were excluded if an intervention's primary focus was unrelated to goal-setting, or if the intervention included goal-setting techniques as secondary components of a larger intervention (i.e., stated that goal-setting was used but did not articulate how or how often). Furthermore, for inclusion, the practice of goal-setting within the intervention had to be patient driven or executed collaboratively with the patient and

had to be individually focussed and measured (group interventions were included only if they also involved individual goal-setting). Interventions that sought to elicit behaviour change in combination with a pharmacological or surgical treatment were excluded from this review. Studies including a control-group had to compare the intervention to usual care to be included. Studies were included regardless of treatment intensity, duration and mode of delivery of the intervention. Only studies published in English were included.

2.4.3.1.2 Types of Participants.

Adults diagnosed with T1DM or T2DM.

2.4.3.1.3 Types of Outcome Measures.

Studies were included that reported any of the following primary outcome measures: average blood glucose levels/ glycaemic control as measured by glycated haemoglobin level (HbA1c) or average number of hyperglycaemic/ hypoglycaemic episodes. Studies were also included if they reported any of the following secondary outcomes measures: body mass index (BMI)/ body weight, physical activity or self-care behaviours as identified by Grant et al. (2013) (carbohydrate counting and awareness, insulin dose adjustment, self-monitoring of blood glucose, managing hypoglycaemia, managing equipment and injection sites or accessing health care).

2.4.3.2 Information sources and search strategy.

Systematic searches were conducted using the following electronic databases: Ovid MEDLINE (1946- January 2016), PsycINFO (1887- January 2016), EBSCO CINAHL (1961- January 2016), EMBASE (1947- January 2016) and PubMed (1946- January 2016). The search strategy for each database can be seen in Appendix III. The reference list of a previous review was checked as this study included goal-setting

interventions targeting T2DM (Miller & Bauman, 2014). Backward and forward citation searches of the included studies were conducted.

2.4.3.3 Study selection process.

All citations were imported into a reference management software package (EndNote X7.4) and all duplicates were removed. In the first screening stage, all titles of the search results were examined by MF and clearly irrelevant titles were removed. All remaining articles were screened in the second screening stage.

In the second stage, all titles and abstracts were screened by MF with 10% of the articles being double screened by a second reviewer (JMS or MB) using the 'Covidence' online systematic review management system (www.covidence.org/). Any discrepancies were resolved by discussion between authors until consensus was reached. Based on the title and abstract, studies moved to the third screening stage if they met all eligibility criteria or if there was uncertainty about their eligibility.

In the third stage of the screening process, relevant review articles were obtained in full, and assessed against the inclusion criteria. Full text screening was conducted by MF, with 20% double screened by a second reviewer (JMS or MB) using a form designed for the purpose. Discrepancies were resolved by discussion until consensus was reached. MF conducted backward and forward citation searches of the included studies.

Cohen's Kappa (κ) (Landis & Koch, 1977) was calculated to determine the extent of interrater agreement at stage 2 and 3 of the screening process. Additionally, the number of included and excluded studies at each stage, and reasons for excluding citations in the third screening stage were recorded and reported in a PRISMA flow chart.

2.4.3.4 Data extraction process.

A data extraction form (Appendix IV) was developed based on the Workgroup for Intervention Development and Evaluation Research (WIDER) recommendations for reporting intervention components (Albrecht, Archibald, Arseneau, & Scott, 2013). Data were extracted by one reviewer (MF) and independently checked by another (JMS or MB). In the case of discrepancies, consensus was reached through discussion.

Extracted data included: author, publication year, study design, participant and provider information, detailed description of the interventions and participants (setting, mode of delivery, intensity, duration, adherence/fidelity, description of the intervention content and development), a description of the control condition if applicable, and outcome data. The trial outcomes and effect sizes, where possible, were extracted from studies or calculated using reported means, standard deviations, and sample sizes at baseline, post-intervention and at other reported measurement points of experimental and control conditions if applicable (Borenstein, Hedges, Higgins, & Rothstein, 2009).

The BCTTv1 (Michie et al., 2013) was used to code BCTs in the included in the interventions from the ‘goals and planning’ and the ‘feedback and monitoring’ BCT clusters. The BCT coding was completed independently by two coders (MF and CF), who had completed online training in BCT coding, using a data extraction form designed for the purpose (Appendix IV). Each BCT was coded every time it appeared in an intervention, so it was possible that the same BCT could be coded more than once. Cohen's Kappa (κ) (Landis & Koch, 1977) was calculated to determine the extent of interrater reliability prior to resolving discrepancies, and discrepancies were discussed until 100% agreement was achieved.

2.4.3.5 Critical Appraisal.

The quality of the studies in this review was assessed to avoid or minimise the impact of studies that were not rigorously conducted on conclusions of this review. All included studies were assessed using the Cochrane 'Risk of bias' tool described in The Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2008) to assess randomisation procedures, bias, allocation, outcome assessors, reporting of findings and losses to follow up. The risk of bias was assessed and filled out as part of the data extraction form by MF and independently checked by another reviewer (MB and JMS). In the case of discrepancies, consensus was reached through discussion.

Based on the Cochrane recommendations (Higgins & Green, 2011), the outcomes of the quality assessment did not result in studies being excluded, as only a limited number of studies were identified as being relevant for this systematic review. However, details related to the quality appraisal are provided to allow readers to determine the weight that should be assigned to each study included in the review.

2.4.3.6 Data Analysis.

2.4.3.6.1 Measures of treatment effect.

Following Cochrane recommendations, data from different study designs were not pooled together to assess effectiveness (Higgins & Green, 2008). Therefore, only data from the included RCTs were pooled using meta-analyses where appropriate and feasible (Higgins et al., 2011). Each outcome measure was analysed separately using data reported at the follow-up time point which occurred immediately at the end of the intervention period.

For the RCT reporting the primary outcome of averaged blood glucose levels, mean differences between groups and the 95% confidence intervals (95% CI) were reported. Where no standard deviations were reported, standard deviations were

calculated using the methods described in The Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2008). Blood glucose outcomes were reported on the exact same scale (HbA1c) and were thus combined using mean differences (MDs) in a meta-analysis.

RCTs reporting body weight outcomes were expected to use different measuring scales (kilo grams or BMI) and were thus combined using standardised mean differences (SMDs) also known as Hedges' (adjusted) g. Confidence intervals (CIs) of 95% were calculated.

As heterogeneity between study effects and populations was assumed, pooled effect sizes used random effects models (inverse-variance approach based on weighted SMDs and odds ratios) using RevMan software (version 5.1; Review Manager, 2011).

If insufficient data was available for pooling effect sizes, or if outcome measures were heterogenic, data were combined in narrative syntheses per outcome measure.

Following Cochrane recommendations (Higgins & Green, 2008), all data from the pre-test post-test designed studies were combined in narrative syntheses.

2.4.3.6.2 Assessment of heterogeneity.

The I2 test statistic was used to indicate the percentage of total variation explained by any identified heterogeneity (Higgins & Green, 2008).

2.4.3.6.3 Assessment of publication bias.

To test the robustness of the findings, risk of publication bias analyses were conducted within Comprehensive Meta-Analysis (CMA) software (version 3). Funnel plot graphs were generated. In the absence of bias, the plot should resemble a symmetrical (inverted) funnel (Hopewell, Loudon, Clarke, Oxman, & Dickersin, 2009). A test of statistical significance for funnel plot asymmetry was performed using Egger's tests (Egger, Smith, Schneider, & Minder, 1997). Additionally, Rosenthal's 'fail-safe

N', was calculated which indicates the number of missing studies having zero or non-significant results, that would need to be retrieved and incorporated in the analysis before the p-value becomes nonsignificant (Rosenthal, 1979).

2.4.3.6.4 Behaviour change techniques analyses.

To assess the frequency of use per BCT across the interventions, the number of times each BCT was coded was summed. To assess the average number of times a BCT was used within an intervention, the total number of times each BCT was coded was summed and divided by the number of interventions in which it was identified.

Pearson's correlation coefficient (two-tailed) was used to investigate the relationship between the numbers of BCTs coded in the interventions (Sedgwick, 2012), and the mean outcome scores for the primary outcome measure of average blood glucose levels (HbA1C). This analysis was based on a similar approach used in previous work (Dombrowski et al., 2012) to assess whether an increase in BCTs was associated with an increased improvement in HbA1C.

Subgroup analysis was selected as a method to examine relative effectiveness of different BCTs on outcomes. To ensure rigour, subgroup analysis would only be implemented if a meta-analysis was conducted with 10 or more studies (Higgins & Green, 2011).

2.5 Study 2: Exploring implementation of goal-setting in practice

2.5.1 Aims and objectives of study 2.

The systematic review and meta-analyses conducted in study 1 offer valuable information regarding the effect and active content of existing goal-setting interventions targeting diabetes outcomes in T1DM and T2DM. However these methods provide limited insights regarding the quality with which interventions are implemented and

delivered and how goal-setting is currently addressed in routine diabetes care (Bellg et al., 2004). Exploring the implementation of goal-setting within DAFNE, a prominent T1DM DSME programme that is part of routine care in Ireland, can create a better understanding of the application of goal-setting strategies in a T1DM care setting. With this in mind, study 2 aimed to explore the content and the fidelity of delivery of the goal-setting component of DAFNE.

- Specific objectives:
    - Identify the active content of DAFNE's goal-setting component in terms of BCTs (Michie et al., 2013).
    - Assess the overall fidelity of delivery of the goal-setting sessions, using a checklist of manual-identified BCTs.
    - Assess variation in fidelity according to educator, session type, and specific BCTs.
    - Identify implemented BCTs not specified within the intervention-manual.

2.5.2 Approach to study 2.

DSME is an area of routine diabetes care in which goal-setting has been structurally implemented (Grant et al., 2013). The overall effectiveness and implementation of DSME programmes has been investigated in previous research, particularly for T2DM (Chrvala et al., 2016). However, complex interventions, like DSME, usually consist of a number of components which operate both independently and inter-dependently (MRC, 2000). How individual components such as goal-setting are implemented and received within these programmes remains unclear. Therefore study 2 focuses on exploring the implementation of the goal-setting component of DAFNE, a widely implemented T1DM DSME programme that is part of routine care.

DAFNE embraces goal-setting as one of its core components (Oliver & Thompson, 2009). However, to optimise DAFNE, research recommends that more attention should be paid to factors within DAFNE that are likely to contribute to behaviour change (Speight et al., 2010); an objective that goal-setting strategies are targeting (Latham, 2003). To improve or further implement an intervention, it is important to establish which components are the active ingredients and how they are exerting their effects (Craig et al., 2013). Therefore, study 2 set out to utilise the BCTTv1 (Michie et al., 2013) to code the active content of the goal-setting component of DAFNE as listed in the programme manuals. Using the BCT-taxonomy to code the active content of the goal-setting component is a novel but necessary approach, as it provides clarity around the mechanisms by which behaviour is suggested to change (Craig & Petticrew, 2013; Michie et al., 2013) and will create a clearer view of how goal-setting strategies are currently applied in a healthcare context.

Additionally implementation fidelity must be addressed to assess whether the active content is being implemented as intended (Bellg et al., 2004). Therefore, study 2 set out to assess implementation fidelity and characteristics of the delivery of the goal-setting component of DAFNE, to assess how goal-setting techniques are implemented in practice (Bellg et al., 2004; Campbell et al., 2000). Within the area of smoking cessation, recent studies utilised BCT-taxonomies to reliably describe intervention content, and systematically assess implementation fidelity by comparing active content of treatment-manuals with the transcripts of corresponding smoking cessation support sessions (Lorencatto, West, Bruguera, & Michie, 2014; Lorencatto et al., 2013). Guided by this research, this study set out to assess implementation fidelity of the goal-setting component of DAFNE by observing a series of DAFNE goal-setting sessions, and

comparing DAFNE-manual identified BCTs with BCTs delivered in corresponding observations and transcripts of audio-recorded DAFNE goal-setting sessions.

2.5.3 Procedure.

2.5.3.1 Study Design.

This study followed a descriptive and observational design in which content from the intervention manuals of the goal-setting component of the DAFNE programme was specified in terms of BCTs and fidelity of delivery was assessed by comparing this content, with corresponding observations and transcripts of audio-recorded DAFNE sessions.

2.5.3.2 Recruitment.

2.5.3.2.1 Clinic recruitment.

Seven diabetes clinics offer DAFNE within the Republic of Ireland. Five clinics were approached to participate in the study, by emailing an invitation letter to the head physician of the clinic (Appendix VI). Clinics were selected based on the number of DAFNE courses that was expected to be provided within the study timeframe, and geographic accessibility. One clinic opted out of the study as no DAFNE courses would be offered during the timeframe of the study and four clinics agreed to partake in the study. The final sample consisted of three clinics, as one clinic failed to communicate an altered starting date of the DAFNE course that took place within the study's timeframe.

2.5.3.2.2 Participant recruitment.

Participants in this study were defined as DAFNE educators and DAFNE participants. Educators were trained staff (dieticians or diabetes nurses) delivering DAFNE courses and DAFNE participants were people with T1DM, attending a DAFNE-course. DAFNE educators were approached via email through the head

physician of the clinic. DAFNE participants were asked to consent to an observation/ audio recording of DAFNE's goal-setting component in person on the first day of the DAFNE course.

Due to the limited number of DAFNE educators available in Ireland and the limited number of offered DAFNE courses within the timeframe, a convenience sampling strategy was utilised based on participants' willingness to take part in the study.

2.5.3.3 Participants.

A total of six female educators were recruited, four of whom actively delivered the goal-setting component and two educators who took an assisting role in these sessions. A total of 74 DAFNE participants were included in the sessions that were observed and audio-recorded for the study.

2.5.3.4 Materials.

2.5.3.4.1 DAFNE's goal-setting component.

The DAFNE course is delivered over five consecutive days and involves 38 hours of structured education. The course content is spread over 21 sessions, with each day consisting of a number of sessions. DAFNE is delivered by a diabetes specialist nurse, a dietitian and a doctor, all of whom have undergone training in delivering the DAFNE-curriculum. Goal-setting is briefly mentioned in an introduction session on day one, but is fully addressed in two sessions later in the week. Within the first goal-setting session, DAFNE participants are taught the principles of goal-setting and behaviour change. They follow up on this in the second session, by writing down a goal and developing an action-plan to achieve this goal. In all included centres, the dietician took responsibility for the delivery of both goal-setting sessions.

2.5.3.4.2 DAFNE-programme manuals.

The manuals and workbook of the DAFNE sessions along with study approval were obtained from the DAFNE office UK. The manuals are guidance documents for DAFNE educators, providing a written plan specifying the procedures educators have to follow and behaviours they should engage in when delivering the DAFNE sessions. The DAFNE workbook is a document for participants containing instruction and exercises relating to particular DAFNE topics such as writing down goals and action-plans.

2.5.3.5 Procedure

2.5.3.5.1 BCT coding of the DAFNE manuals.

MF and one other researcher (EC) independently coded the two goal-setting sessions in the DAFNE manual and workbook using the BCTTv1 (Michie et al., 2013). Both coders had completed online BCT-coding training. Educators' behaviours and procedures as specified in the manuals were labelled as operationalisations of BCTs. These operationalisations were classified under the different BCTs. This was conducted by examining the description of each BCT and assessing if any behaviours or procedures prescribed in the DAFNE manuals corresponded with this description (Sweeney-Magee, Kale, Galton, Hamill, & Gilbert, 2016).

Agreement was registered if both coders identified the same BCT within a section of text. Disagreement was registered if one coder identified a BCT while the other reviewer had not identified this BCT or had identified a different BCT. Disagreements were resolved through discussion. The identified BCTs, and details on their manual specified delivery by the educators, were put into two fidelity checklists, each representing one goal-setting session (due to copyright, the fidelity checklists cannot be made available for publication).

2.5.3.5.2 Observations/ audio recordings.

DAFNE goal-setting sessions were observed and audio-recorded between October 2016 and October 2017. Informed consent for audio-recording was obtained from the educators delivering the DAFNE course, and the participants attending the course. If consent was obtained from all parties, the researcher would directly observe the goal-setting sessions and audio-record the sessions simultaneously. If any DAFNE participants did not consent to an audio-recording, sessions were observed only and rated for fidelity during the observation.

A total of 20 individual goal-setting sessions across a total of ten DAFNE courses were observed. Sixteen sessions were audio-recorded using a discrete recording device. All audio-recordings were transcribed verbatim by MF and all identifying information was removed. Four sessions were observed without an audio-recording taking place as consent for audio-recording was not obtained from 100% of the DAFNE participants present in the observations.

2.5.3.6 Analysis

2.5.3.6.1 BCT coding of the DAFNE manuals.

After coding the manuals using the BCTTv1 (Michie et al., 2013) inter-rater reliability was calculated between the coders using Cohen's kappa (Landis & Koch, 1977).

2.5.3.6.2 Fidelity of delivery.

Using a checklist of manual-specified BCTs, fidelity of delivery for both DAFNE goal-setting sessions was measured by comparing the BCTs coded within the DAFNE-manual and workbook of each session and BCTs delivered in practice during the observations of these sessions.

To address quality of BCTs delivery, and to take into account that BCTs may be delivered wholly or in part (Michie, West, Sheals, & Godinho, 2018) manual-specified BCTs were rated as delivered (1; delivered in full, beyond all reasonable doubt), partly delivered (0.5; delivered in all probability but evidence not clear, or delivered in part) or not delivered (0). This coding scheme followed examples from previous work (Keogh, Matthews, & Hurley, 2018; Wood et al., 2015). Fidelity scores for each BCT were calculated as the number of operationalisations of each BCT delivered by the educator, divided by the total number of operationalisations classified within each BCT (Sweeney-Magee et al., 2016). A total fidelity score was calculated per session by adding the fidelity scores of all BCTs in each session and dividing this by the total amount of BCTs coded. Twenty percent of the transcripts were double rated by one other independent researcher (EC) and inter-rater reliability was calculated using Cohen's kappa (Landis & Koch, 1977). Discrepancies were resolved through discussion.

Overall fidelity of delivery was calculated as an average score across all sessions by adding the scores of all goal-setting sessions and dividing this by the total number of observed sessions; 20. Variation in fidelity was documented according to educator and session type by comparing averaged fidelity scores. In addition, fidelity of delivery was assessed per type of BCT across all sessions (Michie et al., 2013), by dividing the amount of times each BCT was delivered across all observations, by the amount of times each BCT was expected to be delivered across all observations if fidelity was 100%. Fidelity scores were expressed as a percentage (percentage of manual-specified BCTs delivered in practice).

Session duration was documented for each observation, and average duration was calculated. Pearson's correlations were completed to explore the relationship

between fidelity scores and session-duration (Sedgwick, 2012).

The transcripts from the audio-recorded sessions were coded for additional BCTs not included within the manuals, using the BCTTv1 (Michie et al., 2013).

2.6 Study 3: Qualitative exploration of DSME providers' perspectives on the implementation of goal-setting

2.6.1 Aims and objectives of study 3.

The results from study 2 provide valuable insights into the active content and implementation fidelity of goal-setting strategies in a T1DM DSME context. However, to increase our understanding of possible implementation issues of goal-setting in this context, it is useful to explore HCPs' perspectives on the application of goal-setting strategies in DSME (Reimers et al., 1987). Therefore, study 3 aimed to explore educators' perspectives on the implementation of goal-setting strategies supplemented by action-planning within the DAFNE structured DSME-programme.

- Specific objectives:
    - Explore how DAFNE educators experience the delivery and practical application of goal-setting and action-planning components within DAFNE.
    - Explore educators' views on the quality and usefulness of goal-setting and action-planning components within DAFNE and DSME.
    - Explore views on possible improvements to goal-setting and action-planning components.

2.6.2 Approach to study 3.

Shaped by the quantitative findings from study 2, study 3 set out to create a deeper understanding of the implementation and fidelity issues of goal-setting within

DAFNE and DSME. HCPs' judgments of a DSME programme's acceptability could influence their interest and willingness to deliver a programme and implement it with fidelity (Reimers et al., 1987). Exploring HCPs' views on the operationalising and implementation of goal-setting and action-planning strategies in DSME could provide insights into fidelity levels, as well as guide DSME-programme optimisation. Furthermore, barriers and facilitators to successful implementation of goal-setting strategies in diabetes support could be assessed.

A qualitative research design was applied to study 3, to explore DAFNE educator's perspective on goal-setting in DAFNE and DSME. Qualitative research designs are more appropriate for exploring experiences and perspectives of key stakeholders, and can provide a deeper understanding of barriers and facilitators to the implementation of goal-setting strategies in a diabetes context (Braun & Clarke, 2013; Yardley & Bishop, 2015),

2.6.2.1 Ontology and epistemology

Qualitative research can be underpinned by different ontological and epistemological assumptions. This refers to the theories about the nature of reality and knowledge. Ontology refers to assumptions of whether or not reality exists separate from human perspectives and understanding, while epistemology refers to assumptions around what constitutes as legitimate knowledge and what it is possible to know. This research took a critical realist ontological approach (Braun & Clarke, 2013), which assumes that a separate reality exists, but can only be partially accessed as all knowledge is socially influenced and context dependent. Although context dependant, critical realism assumes that research findings should be approached as authentic and reliable for this context (Braun & Clarke, 2006). An equivalent epistemological assumption of contextualism, as described by Braun and Clarke (2013), is underpinning

study 3. Knowledge is assumed to be perspectival and will most likely emerge from context. However, while a single definite truth is difficult to reveal through research, knowledge gained from this research is assumed to be true in this context and therefore valid in creating a knowledge base. Therefore, the data from this research, while contextually influenced, can be significant for future directions of DSME and diabetes support research or optimisation.

From a critical realist perspective, combining the quantitative methods from study 2 and 3 with qualitative research strategies can provide a more complete understanding of a phenomenon. As critical realism assumes that in part a separate reality can be assessed, combining quantitative and qualitative measures offers a good approach to knowledge building. Quantitative and qualitative methods can be combined to reveal different facets of the same reality and also to examine reality from different perspectives (McEvoy & Richards, 2006). In this research, the quantitative data from study 1 and 2 aimed to assess the overall effectiveness of goal-setting interventions, the relationships between different types of goal-setting and outcomes, and asses the current implementation of goal-setting strategies in a DSME context. The qualitative data can complement these findings by exploring HCPs' perspectives on this effectiveness and implementation in an Irish DSME healthcare setting.

2.6.2.2 Approach to data collection and analysis

Semi-structured one-to-one interviews were selected as the most appropriate data collection method for a number of reasons. Firstly, Braun and Clarke (2013) suggest that interviews are the most frequently used strategy for 'exploring, understanding and perception' categories of research questions. As the aim of this study was to explore educators' perspectives on the implementation of goal-setting strategies supplemented by action-planning within DAFNE, interviews were thus suitable.

Additionally, interviews tend to generate rich and detailed data about individual experiences (Braun & Clarke, 2013), which is vital in a relatively understudied area as HCPs' perspectives on goal-setting in DSME.

The one-to-one interview structure facilitates an environment in which participants are able to express individual opinions without the social desirability biases that could surface in group based data collection methods such as focus groups. When delivering DAFNE, educators tend to deliver courses within a team or within pairs. In most cases, one educator takes responsibility for the goal-setting component while the other educator assists in these sessions. Therefore, socially desirable responses could be imminent, as educators may not want to provide negative feedback on a component that is delivered by their team member. Finally, from a feasibility point of view, DAFNE educators are based within several locations in the Republic of Ireland and are often exposed to high workloads. Therefore, it would have been difficult to set a time at which multiple educators would have been available to attend a focus group set-up.

The generated data was analysed using thematic analysis (TA). TA is a method for identifying, analysing and reporting patterns or themes within data and allows for rich description of the data set. TA is recommended for relatively unexperienced qualitative researchers as it is flexible but remains a theoretically and methodologically rigorous qualitative method of analysing data (Braun & Clarke, 2006).

Braun and Clarke (2006) define a theme as an important aspect in the data that relates to the overall research topic. Thematic codes can be driven by theory, by prior research, or inductive (data-driven). An inductive or "bottom up" approach was utilised in this study as it emphasizes the content of the text, and it provides a more succinct summary of the explicit content of the data. Additionally, themes can be identified on a latent/interpretative level or a semantic/explicit level (Braun & Clarke, 2006). Within

this research, themes were mainly identified on a semantic level, meaning that themes represented the explicit meaning of the data, and the researcher did not aim to identify codes beyond what was said by the participants. Codes that are closely related to the content of the raw data increase the probability that data will be encoded in a similar way by different people and reduce potential contamination factors (Braun & Clarke, 2006). Additionally, exploring educators' perspectives on the implementation of goal-setting techniques in DSME is a relatively understudied area (Malemute et al., 2011). Therefore a data-driven approach was particularly suitable for study 3, as analysing the data within a pre-existing theoretical framework deemed challenging given the limited application of theory in this area. Additionally, the results of this type of semantic qualitative analysis tend to be more accessible to a wider audience than other qualitative methods (Braun & Clarke, 2013). Since this research aims to reach a wider audience in the areas of psychology, medicine and health promotion/education, this type of analysis is particularly suitable for this project.

Study 3 was reported using the COnsolidated criteria for REporting Qualitative research (COREQ) checklist (Tong, Sainsbury, & Craig, 2007) (Appendix XII) to ensure rigour in reporting on how the study was conducted.

2.6.3 Procedure.

2.6.3.1 Recruitment and participants.

Eighteen DAFNE educators operate in Ireland across 7 centres. Due to this limited number, a convenience sampling strategy was utilised and educators were selected based on centre-participation and on willingness and availability to participate in the study. Four diabetes centres were invited by emailing an invitation letter (Appendix X) to the head physician. Centres were selected based on geographic location and previous participation in study 2.

Four centres agreed to take part in the study. All educators operational in the 4 diabetes centres (n=11) were approached by distributing study information letters (Appendix XI) via email. Ten educators responded and agreed to participate. As is common in qualitative sampling methodology, recruitment continued until data saturation was reached; saturation was defined in the current study as no new themes being identified in two successive interviews (Glaser, Strauss, & Strutzel, 1968). Transcripts were reviewed after each interview, and initial analysis was conducted after each interview in an iterative fashion. Data saturation was reached after participant 8 as no new themes were identified in the final 2 interviews (Glaser et al., 1968).

2.6.3.2 Data collection.

Semi-structured interviews were conducted between July 2017 and February 2018 by MF. A topic guide, following examples from other qualitative research (Morrissey, Glynn, Casey, Walsh, & Molloy, 2018) and informed by the findings from study 1 and 2, was used to explore educator's experiences of delivery and application and views on usefulness and quality of goal-setting strategies in DAFNE for all interviews. The topic guide was reviewed by a member of the research team with significant qualitative research experience (JMS) and piloted on the first participant to judge suitability. To be responsive to the data, an iterative approach was used (Ziebland & McPherson, 2006), and a few questions were added to the topic guide as new ideas emerged from early data exploration. The final topic guide can be found in Appendix XIII.

Eight interviews were conducted face-to face in a hospital, university or primary care centre setting, and two interviews were conducted via telephone. The interviews lasted an average of 31 minutes (range 21-39) and were audio-recorded with

participants' consent. Recordings were transcribed in full, partially by the main researcher (MF) and partially by an external company.

2.6.3.3 Data Analysis

Inductive or "bottom up" thematic analysis was utilised in this study following guidance from Braun and Clarke (2013). In identifying themes, study 3 followed all five stages of TA: familiarisation, generation of codes, searching for themes, reviewing themes and defining themes.

2.6.3.3.1 Familiarisation

Familiarisation was achieved by the main researcher (MF) transcribing the first 3 interviews of the study and by repeatedly reading all transcripts of the interviews in an active manner to identify possible meanings and patterns. Notes were made at this stage to highlight emerging ideas regarding possible codes or themes.

2.6.3.3.2 Generation of codes

NVivo software (version 11) was used to organize and code the transcripts and facilitate analyses and comparison of relationships between codes. Coding followed an inductive data-derived approach, with the main investigator (MF) creating codes reflecting the semantic content of the data. Initial codes were categorised under the three main objectives of the study. After coding all transcripts, similar codes were collated together under slightly broader code labels. Before moving to the next stage of the analysis, codes were discussed with a second researcher with a high level of qualitative research experience (JMS).

2.6.3.3.3 Searching for themes

Within this phase, relationship between codes, themes and different levels of themes were identified. In line with TA guidelines (Braun & Clarke, 2013), data pattern frequency, as well as level of meaning for answering the research questions, was taken

into account in theme development. Some initial codes became main themes, sub-themes or were discarded.

2.6.3.3.4 Reviewing themes

This phase involves the final refinement of the themes. In collaboration with a second researcher (JMS), themes were visualised in a potential 'thematic map' leading to the development of 5 broader overarching themes. Subsequently, a randomly selected 20% of the original transcripts were checked against the generated themes by MF and JMS, to aid discussion and refinement, and to check whether themes represented the transcripts accurately.

2.6.3.3.5 Defining and naming themes

Quotes from the data within each theme were revised to determine if they formed a coherent pattern. If quotes did not seem to fit the theme, they were either relocated to an already existing theme or code, or eliminated. The essence of each theme was identified, leading to final names and definitions of the themes. Sub-themes were identified to provide structure and hierarchy of meaning in larger or complex themes.

2.6.3.3.6 Write-up

The final themes were written up using an illustrative approach. Quotes were picked based on how well they illustrated the themes. Furthermore, efforts were made to choose quotes from a wide range of participants.

2.7 Ethical Considerations throughout the project

This research followed the ethical considerations of Emanuel, Wendler, and Grady (2000) framework for evaluating the ethics of health research with human participants. The seven requirements for ethical research according to the framework are as follows:

1. Value must be added by the research in terms of knowledge or health improvements
2. Scientifically validity must be present and the research must be methodologically rigorous.
3. Fair participant selection must take place and must be guided by scientifically based objectives and potential risks and benefits should be considered to avoid disproportionate distribution of vulnerable or privileged groups.
4. The risks and benefits ratio to participants and society should be favourable.
5. Independent people with the power to approve, amend or terminate studies should ethically review all research.
6. Informed consent: participation in the research must be voluntary and adequately informed
7. Respect for participants must be shown by shielding their privacy, having every opportunity to withdraw, and monitoring participants' well-being

In this research project, study 2 and 3 entailed the recruitment of participants. Therefore, ethical approval was sought and obtained for data collection within these studies from the NUI Galway Research Ethics Committee Galway, the Galway University Hospitals Clinical Research Ethics Committee, the St. Vincent's Healthcare Group (SVHG) Hospital Research Ethics Committee and the St. Vincent's Healthcare Group (SVHG) Nursing Research & Innovation Committee. For study 2 and 3 the main ethical concerns were related to scientific validity, informed consent, fair participant selection, respect for participants, and confidentiality and anonymity.

2.7.1 Scientific validity

The BCTTv1was utilised to systematically asses implementation fidelity in study 2, and the CORE-Q checklist was utilised in study 3 to ensure research transparency and methodological rigour in this research.

2.7.2 Informed consent

The achievement of informed consent from patients and potential research participants is considered a basic requirement in clinical care and clinical research (Kent, 1996). Therefore, this research project ensured that all participants gave voluntary, informed consent before participating in the research studies (World Medical Association, 2001). Healthcare providers and a population with a chronic condition, the target populations for this research, may have been contacted and recruited for several studies. This could affect the disposition of DAFNE educators and people with diabetes to partake in research. Therefore, the importance of informed and voluntary consent, and sufficient time to form a decision, were central to facilitate educators or people with diabetes to choose, independently, to take part in research which was of interest to them (Hynes, 2015).

Information related to each study and to informed consent was clear, and was provided to participants where possible, in more than one form (e.g. in writing and oral) before written consent was obtained. Study information contained details related to the purpose and methods of the study, risks and benefits of participation and detailed information on what participation would involve and how their data would be treated. Furthermore, potential participants were made aware that participation was voluntary and consent could be withdrawn at any time during the research without giving a reason. Participants within the diabetes patient group were made aware that their future care would not be impacted in any way by their decision to participate or not. All

participants were given the opportunity to ask questions to ensure that the information provided was understood adequately (Applebaum, Lidz, & Meisel, 1986).

Potential participating DAFNE participants (people with T1DM following the DAFNE course) in study 2, were given oral information about the study, and an information letter (appendix VII) on the first day of a DAFNE course, after which participants were given the opportunity to ask questions. DAFNE-participants were given 3-4 days to consider whether or not to consent to an audio-recording in study 2. On the fourth or final day of the DAFNE course, people were asked to decide on whether to participate and give consent by signing and returning the consent form.

In study 2 and 3, potential participating DAFNE educators were given a study information letter via email at the time of recruitment (appendix VIII & XI) at least 1 month before written consent was obtained. Educators were encouraged to ask questions if study details were considered unclear or if further information was required. If educators decided to partake in the studies, written consent was obtained on the first day of the DAFNE course in study 2. In study 3, written consent was obtained in person prior to the interviews, or via email if interviews were conducted via telephone.

2.7.3 Fair participant selection

Within this research we aimed to gather the views and perspectives of a varied sample of DAFNE educators and people following a DAFNE course. Therefore, the exclusion criteria applied in this research were minimal and participants of different age groups and different backgrounds were included.

2.7.4 Respect for participants

Participants were shown respect in this research by providing accurate and detailed information regarding each study, and by making sure all information was

understood before recruitment took place. Participants' privacy was maintained throughout the studies and participants were given opportunities to withdraw from the studies.

2.7.5 Confidentiality & anonymity

Two studies in this research involved collecting data in the form of audio-recordings, and fidelity scores. Therefore, the secure management of data was of particular importance to this project. The audio-recordings of the goal-setting sessions in study 2, and the interviews in study 3 were recorded using digital recording equipment and the data was immediately saved to a password protected computer. In the process of data-transcription, participants were pseudonymised through the use of participant numbers, and the transcripts were stored on a password protected computer. Consent forms for studies 2, and 3 and filled out fidelity forms for studies 2 were stored in locked location in the University. The small samples size in study 3, and the limited number of active DAFNE educators in Ireland, somewhat posed a challenge to confidentiality. To protect confidentiality, quote labels within the manuscript of study 3 do not contain any detail regarding the participant's characteristics.

2.8 Summary of the chapter

This chapter provided an overview of the study design and details of the methodological approach of each study in this thesis. Furthermore, justifications were provided for the choice of design and methodologies. The aim of the three studies described in this chapter was to assess the effectiveness and explore the implementation of goal-setting techniques in diabetes self-management interventions and a T1DM education programme. A systematic review and meta-analysis, a content and fidelity exploration study and a qualitative thematic analysis study were conducted to address

this aim. The main ethical concerns were related to scientific validity, fair participant selection, respect for participants, confidentiality and anonymity, and informed consent. Measures to address each of these concerns were taken and discussed. The following chapters will consist of the individual studies conducted as part of this PhD.

3. Study 1: Goal-setting in Diabetes Self- management: A Systematic Review and Meta-analysis examining Content and Effectiveness of Goal-setting Interventions

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3.1 Abstract

Background. Goal-setting is recommended and widely used within diabetes self-management programmes. However, empirical evidence around its effectiveness lacks clarity. This review aims to evaluate the effectiveness of goal-setting interventions on diabetes outcomes and to determine which behaviour change techniques (BCTs) are frequently used within these interventions.

Methods. A systematic search identified 14 studies, describing 12 interventions targeting diabetic-control which incorporated goal-setting as the main intervention strategy. Study characteristics, outcome measures and effect sizes of the included studies were extracted and checked by two authors. The BCTTv1 was used to identify intervention content. Meta-analyses were conducted to assess intervention effects on the primary outcome of average blood-glucose levels (HbA1c) and on body-weight.

Psycho-social and behavioural outcomes were summarised in narrative syntheses.

Results. Significant post-intervention improvements in HbA1C were found (-0.22, 95% CI, -0.40, -0.04) across studies. No other main effects were identified. The BCT 'goal-setting (behaviour)' was most frequently implemented and was identified in 84% of the interventions.

Conclusions. Goal-setting interventions appear to be associated with reduced HbA1C levels. However, the low numbers of studies identified and the risk biases across studies suggest more research is needed to further explore goal-setting BCTs in diabetes self-management.

KEYWORDS: Diabetes; Goal-setting; Goal-setting; Interventions; Behaviour change techniques; systematic review

3.2 Background

Diabetes is rapidly becoming one of the most challenging public health issues across the globe (Guariguata et al., 2014). If not treated properly, diabetes can cause health complications such as cardiovascular diseases, foot ulcers, and retina damage. To avoid these complications, it is vital that people diagnosed with diabetes follow treatment regimens to achieve overall healthy levels of blood glucose, also known as glycaemic control. Diabetes treatment consists of ongoing medical care and continuous self-management by the patient (Ahola & Groop, 2013).

Diabetes self-management is a demanding and multifaceted task which includes a variety of self-care activities and skill sets (American Diabetes Association, 2014). Self-management behaviours, including continuous blood glucose monitoring, injecting insulin and exercising, if executed properly, can significantly reduce the risk of diabetes related complications (Funnell et al., 2007). However, despite the known benefits of

careful adherence to a treatment regimen, sub-optimal levels of glycaemic control are commonly detected within people with diabetes (Ahola & Groop, 2013).

The complex nature of diabetes management makes developing effective self-management interventions a challenge. The various behaviours involved can make it difficult for clinicians, researchers, and intervention designers alike to know how best to focus possible interventions and research projects (Grant et al., 2013).

A recent research prioritisation exercise, conducted with diabetes stakeholders, identified ‘goal-setting with patients’ as a priority research focus for behavioural research in diabetes (Mc Sharry et al., 2016). Goal-setting techniques are frequently implemented within diabetes self-management interventions and have been identified as a core component present across structured diabetes education programmes (Grant et al., 2013). Goal-setting techniques are often integrated within larger multi-component programmes and interventions (Avery et al., 2015), but can also be used as a primary intervention strategy (Miller & Bauman, 2014).

The practice of goal-setting is well-defined within goal-setting theory (Locke & Latham, 2002). Goal-setting theory has been used to explain and change behaviour across several domains including health (Strecher et al., 1995). According to Locke and Latham (2002), the process of goal-setting can facilitate behaviour change by guiding people’s effort and attention. However, the effects of goal-setting on achieving outcomes are often moderated by a number of variables. These can range from psychosocial factors such as self-efficacy levels, to the nature of the goals and the implementation of accompanying behaviour change strategies such as planning and feedback provision (Locke & Latham, 2002). For example, setting specific, more challenging, yet achievable goals in terms of behaviour tends to lead to better performance, as compared to easily-achievable goals, or goals focused on vague

outcomes. Furthermore, many of the behaviours we are trying to affect in behavioural interventions such as diabetes self-management, are highly complex and will require careful planning to develop appropriate goal-setting strategies. Therefore, techniques such as action-planning and barrier-identification are essential parts of effective goal-setting practices (Strecher et al.,1995). Additionally, incorporating feedback strategies in goal-setting practices is believed to enhance goal attainment (Locke & Latham, 2002). Many of these behaviour change strategies assumed to moderate the effectiveness of goal-setting practices, are represented in Michie et al. (2013) 'Behavioural Change Technique Taxonomy v1 (BCTTv1)'.

The BCTTv1 provides us with a tool to describe the active content of complex interventions in terms of behaviour change techniques (BCTs). BCTs can be described as apparent, replicable, and irreducible components of interventions that are designed to change or redirect causal processes that regulate behaviour (Michie et al., 2013). According to the BCTTv1, 'goals and planning' and 'feedback and monitoring' are two of 16 broad clusters that contain a total of 16 specific BCTs between both clusters. BCTs such as 'goal-setting, behaviour' and 'goal-setting, outcomes' represent different types of goal-setting, with 'goal-setting, behaviour' described as 'setting or agreeing on a goal in terms of behaviour to be achieved' and 'goal-setting, outcome' defined as 'setting a goal in terms of a positive outcome of wanted behaviour'. Furthermore, BCTs such as 'action-planning' and 'problem-solving' represent strategies that accompany goal-setting by outlining specific plans to reach goals. While there are other strategies for describing intervention content within the field of behaviour change (Kok et al., 2016), the BCTTv1 describes the different types of goal-setting most clearly, and is well suited for coding intervention content retrospectively within cross disciplined intervention research (Kok et al., 2016; McEwan et al., 2016; Michie et al., 2013).

While goal-setting is recognised as a core element of diabetes self-management educational programmes, there is limited evidence available for the effectiveness of goal-setting as a primary intervention strategy to promote diabetes self-management. Avery et al. (2012) conducted a systematic review of interventions aimed at increasing physical activity in adults with Type 2 diabetes. In a set of in-depth analyses, they identified which BCTs were utilized within these interventions and which BCTs may be associated with improvements in average blood glucose levels (measured in glycated haemoglobin level, HbA1c; Avery et al., 2012). The analyses suggested that 'goal-setting and planning BCTs' such as 'review of behavioural goals' and 'goal-setting, behaviour' were associated with improvements in HbA1c. However, these findings solely applied to interventions using physical activity as a strategy for diabetes self-management. While physical activity is a viable self-management option for people with Type 2 diabetes, it is not the only self-management option and other behaviours could be equally essential (Ahola & Groop, 2013). Additionally, these BCTs were incorporated within multi-component complex interventions. It is therefore unclear how effective these goal-setting techniques would be if they were implemented as the primary intervention strategy. A previous systematic review by Miller and Bauman (2014) attempted to address this question by giving an overview of interventions that had incorporated goal-setting as their primary strategy for improving a wider range of self-management behaviours and health outcomes in people with T2DM. While this review provided some information on health and behavioural outcomes following goal-setting focussed interventions, assessing intervention effectiveness was not the primary focus of this review. Therefore, it was largely descriptive and provided little information on the overall effectiveness of goal-setting focussed interventions. Furthermore, this

review provided no information on the actual content of these ‘goal-setting’ interventions in terms of incorporated BCTs.

To our knowledge, no previous review has systemically assessed the effectiveness of goal-setting as a primary intervention strategy to promote diabetes self-management. In fact, Miller and Bauman (2014) highlighted that more systematic research is needed to determine the effectiveness of goal-setting in this context, and the conditions and behaviours for which goal-setting is most effective. Furthermore, no review has attempted to specify the content of goal-setting focussed diabetes self-management interventions using the BCT taxonomy. Specifying intervention content in terms of BCTs can help to clarify what ‘goals and planning’ techniques are mostly implemented and under which conditions goal-setting is most effective. Furthermore, identifying if ‘feedback and monitoring’ BCTs have been incorporated, can help validate the assumed effect of these BCTs on goal achievement. By specifying the presence or absence of BCTs across studies, associations could be made between specific BCTs and higher outcome effects. This could inform future intervention development.

3.3 Aim

The aim of this review was to assess the effectiveness of goal-setting behavioural change interventions on clinical, health, psychosocial or behavioural outcomes in people with diabetes. An additional aim was to identify which “Goals and planning” and “Feedback and monitoring” BCTs are most frequently used in these interventions and which are most effective in improving outcomes.

3.4 Method

A systematic review of intervention studies was conducted. This systematic review and meta-analysis were conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher et al., 2009) (for completed PRISMA checklist see Appendix II). The review protocol was pre-registered with the International Prospective Register of Systematic Reviews (PROSPERO) database (doi: 10.15124/CRD42015027561).

3.4.1 Eligibility Criteria.

3.4.1.1 Types of Studies.

Eligible study designs included randomised controlled trials (RCTs), non-randomised controlled trials, quasi experimental studies or studies with a pre-post design. Based on a recent review by McEwan, et al. (2016), eligible studies were intervention studies utilising goal-setting techniques as the primary intervention strategy to improve health and behavioural outcomes in people with diabetes. The primary focus of the interventions therefore needed to involve setting diabetes self-management goals. Studies were excluded if an intervention's primary focus was unrelated to goal-setting, or if the intervention included goal-setting techniques as secondary components of a larger intervention (i.e., stated that goal-setting was used but did not articulate how or how often). Furthermore, for inclusion, the practice of goal-setting within the intervention had to be patient driven or executed collaboratively with the patient and had to be individually focussed and measured (group interventions were included only if they also involved individual goal-setting). Interventions that sought to elicit behaviour change in combination with a pharmacological or surgical treatment were excluded from this review. Studies including a control-group had to compare the intervention to usual care to be included. Studies were included regardless of treatment

intensity, duration and mode of delivery of the intervention. Only studies published in English were included.

3.4.1.2 Types of Participants.

Adults diagnosed with T1DM or T2DM.

3.4.1.3 Types of Outcome Measures.

Studies were included that reported any of the following primary outcome measures: average blood glucose levels/ glycaemic control as measured by glycated haemoglobin level (HbA1c) or average number of hyperglycaemic/ hypoglycaemic episodes. Studies were also included if they reported any of the following secondary outcomes measures: BMI / body weight, physical activity or self-care behaviours as identified by Grant (2013) (carbohydrate counting and awareness, insulin dose adjustment, self-monitoring of blood glucose, managing hypoglycaemia, managing equipment and injection sites or accessing health care).

3.4.2 Information Sources.

Ovid MEDLINE (1946- January 2016), PsycINFO (1887- January 2016), EBSCO CINAHL (1961- January 2016), EMBASE (1947- January 2016) and PubMed (1946- January 2016) electronic database searches were conducted. The search strategy for each database can be seen in Appendix III. We checked articles cited in a previous review (Miller & Bauman, 2014) and conducted backward and forward citation searches of included studies.

3.4.3 Study Selection.

One author (MF) imported citations into a reference management software package (EndNote) and removed duplicates. In the first screening stage, all titles of the search results were examined and clearly irrelevant titles were removed.

In the second screening stage, 720 titles and abstracts were screened. Ten percent of titles and abstracts were double screened by a second reviewer (JMS or MB) using the Covidence online systematic review management system (www.covidence.org/). Any discrepancies were resolved by discussion between authors until consensus was reached. Cohen's Kappa (κ) was calculated to determine the extent of interrater agreement and a substantial agreement was reached of $\kappa = 0.78$ (Landis & Koch, 1977).

In the third stage of the screening process, relevant review articles were obtained in full, and assessed against the inclusion criteria. Full text screening was conducted by MF, with 20% double screened by a second reviewer (JMS or MB); discrepancies were resolved by discussion until consensus was reached. Initial full text double screening showed a moderate inter-rater agreement of $\kappa = 0.41$ (Landis & Koch, 1977) due to disagreement on study design inclusion. After agreement on study design inclusion was reached, a high interrater agreement of $\kappa = 0.79$ was established. The numbers of articles at each stage can be seen in the PRISMA flow chart (Figure 3.1)

3.4.4 Data Extraction.

A data extraction form was developed based on the Workgroup for Intervention Development and Evaluation Research (WIDER) recommendations for reporting intervention components (Albrecht et al., 2013). Data were extracted by one reviewer (MF) and independently checked by another (JMS or MB). In the case of discrepancies, consensus was reached through discussion. Extracted data included: detailed description of the interventions in published papers (participant information, setting, mode of delivery, intensity, duration, adherence/fidelity, description of the intervention content), a description of the control condition if applicable, and outcome data.

The BCTTv1 (Michie et al., 2013) was used to code ‘goals and planning’ and the ‘feedback and monitoring’ BCTs included in the interventions. The BCT coding was completed independently by two trained BCT coders (MF and CF. Inter-rater reliability was calculated prior to resolving discrepancies ($\kappa = 0.81$; Landis & Koch, 1977). Discrepancies were discussed until 100% agreement was achieved.

The trial outcomes and effect sizes, where possible, were extracted from studies or calculated using reported means, standard deviations, and sample sizes at baseline, post-intervention and at other reported measurement points of experimental and control conditions if applicable (Borenstein et al., 2009).

3.4.5 Critical Appraisal.

All included studies were assessed using the Cochrane risk of bias tool (Higgins & Green, 2008). The risk of bias was assessed by one reviewer (MF) and independently checked by another (MB and JMS). In the case of discrepancies, consensus was reached through discussion.

3.4.6 Data Analysis.

3.4.6.1 Effects of the Intervention.

Following Cochrane recommendations, results from different study designs were not combined in a meta-analysis (Higgins & Green, 2008). Results from the included RCTs were evaluated separately in a meta-analysis if sufficient outcome data were available from at least three studies. Data reported at the follow-up time point which occurred immediately at the end of the intervention period were used for the meta-analyses. Within the meta-analyses, averaged blood glucose level outcomes were reported on the exact same scale (HbA1c) and were thus combined using mean differences (MDs). Other outcomes were expected to be measured using a variety of

scales and were thus combined using standardised mean differences (SMDs) also known as Hedges' (adjusted) g. Confidence intervals (CIs) of 95% were calculated. Results were pooled using random effects models (inverse-variance approach based on weighted SMDs and odds ratios) using RevMan software (version 5.1; Review Manager, 2011). The I2 test statistic was used to indicate the percentage of total variation explained by any identified heterogeneity (Higgins & Green, 2008).

To test the robustness of the findings, risk of publication bias analyses were conducted within Comprehensive Meta-Analysis (CMA) software (version 3). Funnel plot graphs were generated. In the absence of bias, the plot should resemble a symmetrical (inverted) funnel (Hopewell et al., 2009). A test of statistical significance for funnel plot asymmetry was performed using Egger's tests (Egger et al., 1997). Additionally, Rosenthal's 'fail-safe N', was calculated which indicates the number of missing studies having zero or non-significant results, that would need to be retrieved and incorporated in the analysis before the p-value becomes nonsignificant (Rosenthal, 1979).

Data from the pre-test post-test designed studies were combined in narrative syntheses.

3.4.6.2 Behaviour change techniques.

Subgroup analysis was selected as a method to examine relative effectiveness of different BCTs on outcomes. Subgroup analysis would only be implemented if a meta-analysis was conducted with 10 or more studies. Pearson's correlation coefficient was used to investigate the relationship between the numbers of BCTs used and mean outcome scores (Sedgwick, 2012).

3.5 Results

3.5.1 Description of Studies.

3.5.1.1 Results of the Search.

Fourteen studies were included, describing 12 interventions. Two of the included interventions were described in two different publications, Estabrooks et al. (2005) and Glasgow, Nutting, et al. (2004) describe the same intervention, and DeWalt et al. (2009) and Wallace et al. (2009) describe the same intervention. Of these 14 studies, seven were suitable for quantitative meta-analyses. Figure 3.1 shows the PRISMA flowchart visualising the selection process.

3.5.1.2 Included Studies.

Key features of all studies are summarised in Table 3.1. All studies were from high-income countries (11 USA, 1 UK and 2 NL).

3.5.1.3 Description of included Studies.

Included interventions, implemented strategies to set individually focussed diabetes related goals. The settings of the interventions ranged from medical-settings (Corser et al., 2007; Naik et al., 2011) and community health centres (Anderson, Christison-Lagay, & Procter-Gray, 2010) to the home of the patient (Wolever et al., 2010). Five studies used in-person methods only for the delivery of their intervention (Anderson et al., 2010; Corser et al., 2007; Kroese, Adriaanse, Vinkers, van de Schoot, & de Ridder, 2014; Naik et al., 2011; Thoolen et al., 2007), whereas one intervention was solely telephone based (Wolever et al., 2010). The other studies used a mix of delivery modes. The intensity of the interventions ranged from one contact moment in the form of an educational goal-setting session (Corser et al., 2007), to 14 contact moments in the form of phone based goal-setting sessions (Wolever et al., 2010). On average, the interventions included four contact moments. The study designs differed,

eight intervention studies were RCTs (Anderson et al., 2009; Clark, Hampson, Avery, & Simpson, 2004; Estabrooks et al., 2005; Glasgow, Nutting, et al., 2004; Glasgow et al., 2006; Glasgow, Toobert, & Hampson, 1996; Naik et al., 2011; Thoolen et al., 2007; Wolever et al., 2010) and four intervention studies were single group pre-test post-test designs (Anderson et al., 2010; Corser et al., 2007; DeWalt et al., 2009; Kroese et al., 2014; Wallace et al., 2009). The total number of participants included in all studies was 3015. The numbers of participants within each study, ranged from 56 participants (Wolever et al., 2010) to 886 participants (Estabrooks et al., 2005; Glasgow et al., 2004) with 91% of studies recruiting people with T2DM only. All studies had at least 75 percent follow-up in the post intervention measures.

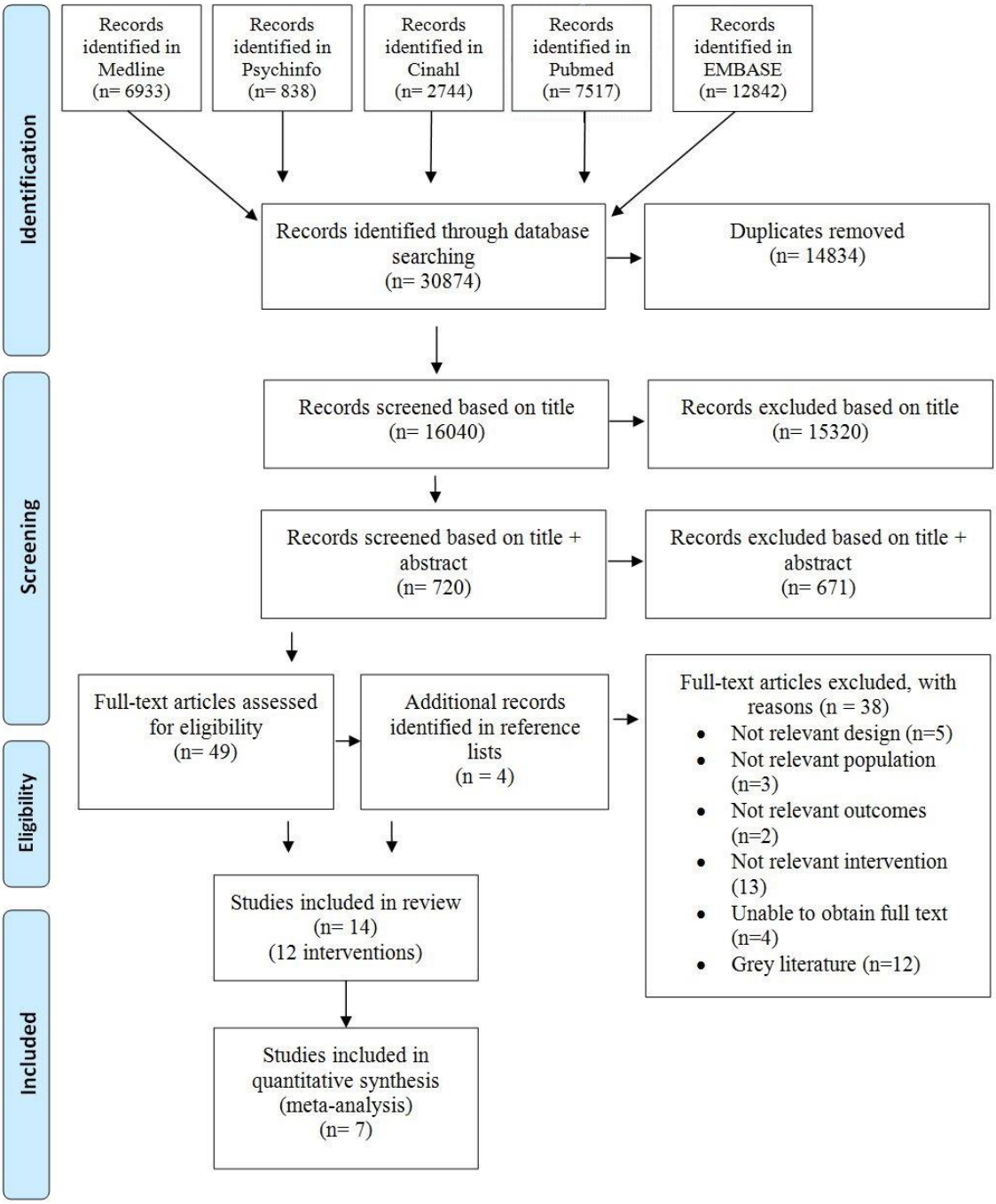

Figure 3.1. Prisma flowchart

Table 3.1.
Study characteristics

Study	**Design**	**Sample characteristics**	**Outcome Measures**	**Intervention summary**	**Intervention setting**	**Mode of intervention delivery**
Anderson et al. (2010)	Single group pre- post-test	T2DM adults (n=488)	HbA1c levels Goal attainment at any follow up visit	6 individual goal-setting and action planning sessions every 1-2 wks., with additional follow-up sessions on a quarterly basis.	Community health centres	In person
Anderson et al. (2009)	RCT; Parallel 2 group pre-post-test	T2DM adults (n=310)	HbA1c levels Self-efficacy (DES-SF; DSMC) Quality of life (PAID)	1 individual baseline assessment to set behavioural goals. 1 follow up meeting to review progress. Additional follow up phone calls once a month.	Medical setting + participants home	In person , by telephone
Clark et al. (2004)	RCT; Parallel 2 group pre-post-test	T2DM adults (n=100)	Physical activity (Diabetes Self-Care Activities Questionnaire + The Physical Activity Scale for the Elderly Questionnaire) BMI	3 (30 min) individual goal-setting meetings at baseline, 12 and 24 weeks 4 (10 min) follow up phone calls for goal review and problem solving	Medical setting + participants home	In person, by telephone
Corser et al. (2007)	Single group pre- post-test	T2DM adults (n=58)	HbA1c	1 (2hr) education goal-setting session in which a decision-support workbook was utilized to guide diabetes goal-setting	Medical setting	In person

DeWalt et al. (2009) & Wallace et al. (2009)	Single group pre- post-test	T2DM adults (n=229)	Self- efficacy	1 (15 min) session to set 1 goal, and action plan for improving diabetes self-management. 2 (14 min) phone follow up sessions at 2 and 4 wks.	Medical setting + participants home/work	In person, via telephone
Estabrooks et al. (2005) & Glasgow et al. (2004)	RCT; 2 group pre-post-test	T2DM adults (n=886)	Self-monitoring of blood glucose (5-item scale from the PRP) Quality of life (PAID-2)	1 (30–45 min) computer guided goal-setting intervention followed by a counselling session (9-10 min) to discuss goal. 2 brief follow-up calls to review progress	Medical setting + participants home	Computer , in person, by telephone
Glasgow et al. (2006)	RCT; 2 group pre-post-test	T2DM adults (n=301)	HbA1c BMI Quality of life (revised Diabetes Distress Scale)	1 computer guided goal-setting intervention (30–45 min) with in-person guidance. 1 brief follow-up call to review progress. 1 tailored letters reinforcing selected goals after 6 wks.	Medical setting + participants home	Computer, in person, by telephone
Glasgow et al. (1996)	RCT: 2 group cluster pre- post-test	T2DM or T1DM adults (n=177)	HbA1c	1 Computer assessment of diet behaviour and relevant strategies to help diet behaviour + video on to barriers to healthy eating, followed by guided individualised goal-setting action planning. 2 brief follow up phone call at 1 and 3 wks.	Medical setting + participants home	Computer, in person, by telephone
Kroese et al. (2013)	Pre-test post-test Single group design	T2DM adults (n=128)	HbA1c Physical activity (Physical Activity Scale for the Elderly (Schuit, Schouten, Westerterp, & Saris, 1997) BMI Self-efficacy	2 (1h) individual sessions assessing patient's knowledge, attitudes and ambivalence 4 (2-h) group meetings lead by nurse (included discussions of domains of self-care and formulating individual action plans to carry out personally set relevant goals with regard to each theme) 3 booster sessions at 1, 3 and 6 months	Medical setting + participants home/work	In person

Naik et al. (2011)	RCT; Parallel 2 group pre-post-test	T2DM adults (n=87)	HbA1c Self-efficacy (The Diabetes Self-efficacy Scale)	4 (70 min) group sessions on goal-setting and action planning every 3 weeks over 3 months. Sessions included individual interaction with clinician discussing DM goal and action plan.	Medical setting	In person
Thoolen et al. (2007)	RCT	T2DM adults (n=195)	BMI	2 (1-h) individual sessions assessing patient's knowledge, attitudes and ambivalence + assessing self-management levels 4 (2-h) biweekly group meetings lead by nurse (included discussions of domains of self-care and formulating, plans to carry out personally set relevant goals with regard to each theme)	Medical setting + participants home	In person
Wolever et al. (2010)	RCT; Parallel 2 group pre-post-test	T2DM adults (n=56)	HbA1c Quality of life (SF-12).	1 phone counselling session discussing long term goals. 13 (30 min) follow up phone counselling sessions, involving goal-setting and action planning	Participants home/ work	Via telephone

3.5.2 Assessment of Risk of Bias in included Studies.

Within this review, the levels of bias varied considerably between studies due to variation in study design or conduct. Overall, blinding (performance bias and detection bias) was considered to have the highest level of risk to bias as most interventions were completed in co-operation with care-givers and clinics. A summary of the risk of bias in all 14 studies is shown in Figure 3.2.

Figure 3.2. Risk of bias summary: authors' judgements about each risk of bias item for each included study.

Legend: (+) Low risk of bias; (-) High risk of bias; (?) Unclear risk of bias.

3.5.3 Publication Bias.

3.5.3.1 Blood-glucose levels.

The *p* value for Eggers test (Egger et al., 1997) was .02, suggesting asymmetry within the funnel plot, which indicates that significant publication bias is likely (Sedgwick, 2013). The funnel plot can be seen in Figure 3.3 (a). The fail-safe N was 10.

3.5.3.2 Body-weight.

The p value for Eggers test (Egger et al.,1997) was .75 which suggests that publication bias could not be detected (Sedgwick, 2013). The funnel plot can be seen in Figure 3.3 (b). The fail-safe N was therefore 0.

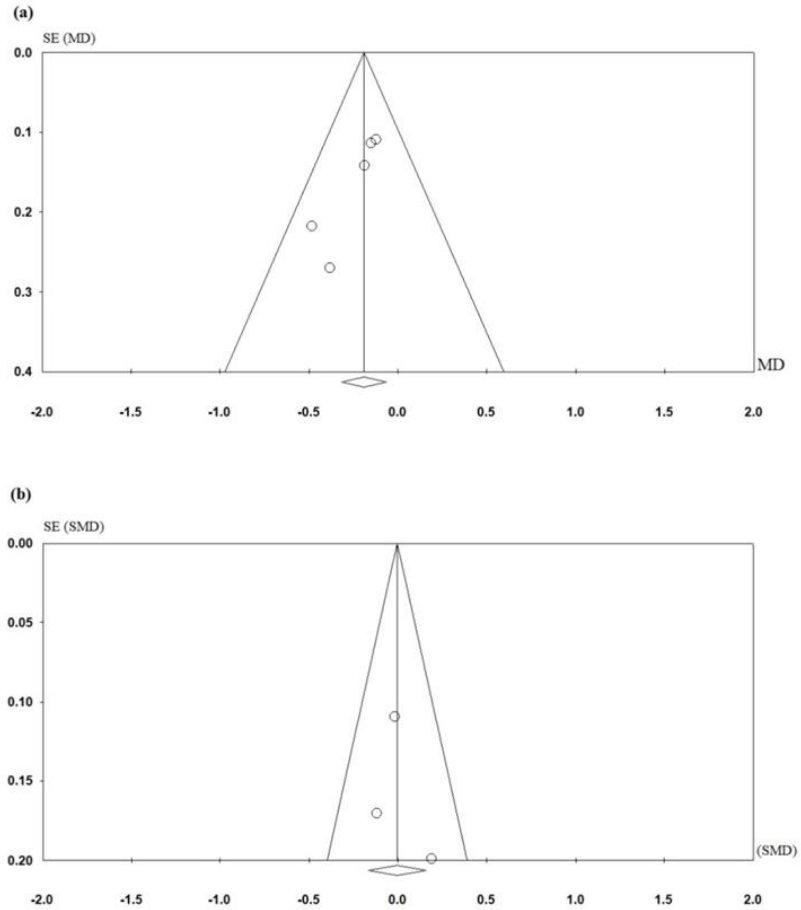

Figure 3.3. Funnel plot for (a) Blood glucose levels and (b) Body-weight

3.5.4 Effects of the Interventions.

3.5.4.1 Clinical Outcomes.

3.5.4.1.1 Average blood glucose levels (HbA1c).

Five RCTs measured HbA1c levels pre- and post-intervention. A meta-analysis of the mean difference between the goal-setting intervention and usual care groups at follow up demonstrated a significant decrease (p = 0.02) in average blood glucose levels. An average decrease in HbA1c was measured of -0.22% (95% CI, -0.40, -0.04). An I2 of 22% was calculated, indicating a low percentage of variation across study results due to heterogeneity rather than chance. Figure 3.4 shows the forest-plot of the effect of goal-setting interventions on HbA1c.

Three single group pre-test post-test studies assessed HbA1c. Anderson et al (2010) reported an average decrease of -0.9% (±0.18%) in A1c per year and concluded that following an individual goal-setting intervention, significantly more people improved in average blood glucose levels (n = 92) than worsened (n = 36). Mean differences were not reported. Kroese et al. (2013) reported no significant change (p= 0.39) at a 15 month follow-up in HbA1C as a result of an individually focussed goal-setting and action-planning intervention within a group setting. Corser et al. (2007) reported no significant change in HbA1c at a 4 month follow up (p=0.22) following a two-hour educational goal–setting session.

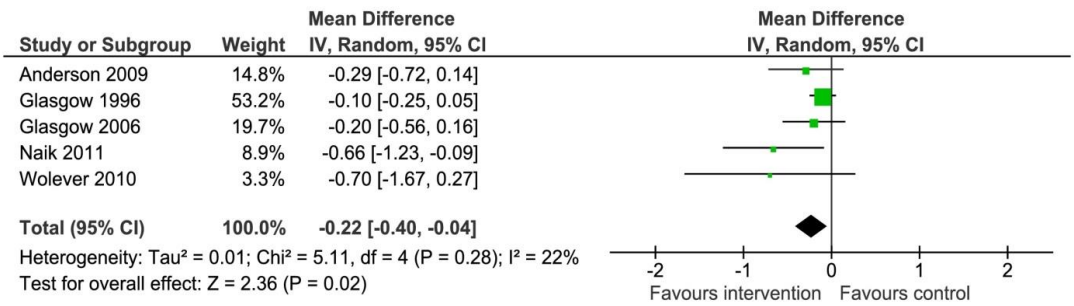

Figure 3.4. Meta-analysis of effect of interventions on HbA1c

3.5.4.1.2 Body weight.

Three RCTs reported body weight. A small meta-analysis of the mean difference between the groups at follow up, comparing goal-setting interventions and usual care, demonstrated no significant changes (MD 0.06, 95% CI −1.17 to 1.28, p = 0.96) in body weight. An I^2 of 0% was measured. Figure 3.5 shows the forest plot of the effect of interventions on body weight.

One study, using a group pre-test post-test design, reported body weight, and reported no significant change (p= .39*;* Kroese et al.,2013).

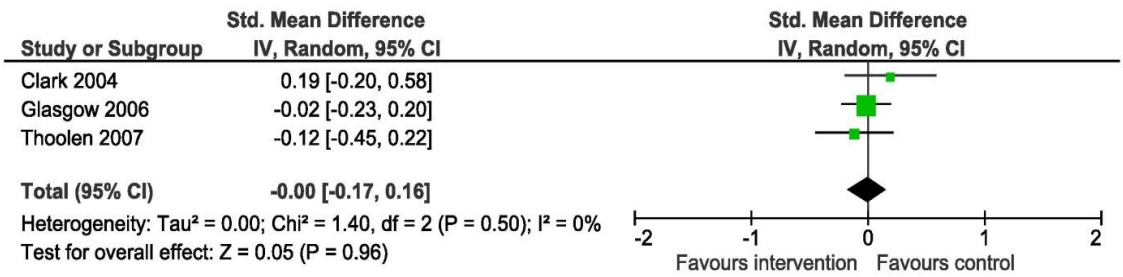

Figure 3.5. Meta-analysis of effect of interventions on body weight

3.5.4.2 Psychosocial Outcomes.

3.5.4.2.1 Self-efficacy.

Two RCTs measured self-efficacy using validated tools (Anderson, Fitzgerald, Gruppen, Funnell, & Oh, 2003; Rapley, Passmore, & Phillips, 2003). Both studies reported significant improvements in self-efficacy. After an individual goal-setting intervention, Anderson et al. (2009) found significant improvements in self-efficacy within the intervention group compared to the control-group (p=0.02). Following a group based goal-setting intervention, Naik et al. (2011) also reported significant improvements in self-efficacy.

Using validated tools (Anderson et al., 2003; Lorig, Chastain, Ung, Shoor, &

Holman, 1989), three pre-test post-test single group intervention studies measured self-efficacy, with two reporting significant improvements. DeWalt et al. (2009) and Wallace et al. (2009) found significant (p= <0.001) positive changes in self-efficacy scores, following an individual goal-setting intervention. Kroese et al. (2013) also found significant post intervention improvements in self-efficacy, but did not provide any average mean scores. Finally, Corser et al. (2007) found no significant improvements in self-efficacy (p=0.158).

3.5.4.2.2 Quality of Life.

Four RCTs assessed the effects of goal-setting interventions on quality of life, using a variety of validated measures (Polonsky, 2000; Ware Jr, Kosinski, & Keller, 1996; Welch, Weinger, Anderson, & Polonsky, 2003) with one study reaching significant increases. Glasgow et al. (2004) found no significant difference in quality of life scores between participants following a computer guided goal-setting intervention and the control group (p=0.75). In a sequential study by Glasgow et al. (2006), in which the previous intervention was altered by adding content such as motivational letters, again no significant changes were found in quality of life (p=0.29). Conversely, Anderson et al. (2009), found that at follow up, the intervention group scored significantly higher than the control group in quality of life (p=0.008). This suggested that their individual goal-setting intervention, supplemented by follow up phone-calls, had a positive effect on quality of life. Finally, the phone-based goal-setting intervention by Wolever et al. (2010), had no significant impact on quality of life.

3.5.4.3 Behavioural Outcomes.

3.5.4.3.1 Physical activity.

One of the included RCTs measured physical activity. Clark et al. (2004) assessed the effect of an individual goal-setting intervention, characterised by individual

meetings and follow up phone calls, on physical activity. Validated questionnaires (Schuit, Schouten, Westerterp, & Saris, 1997) were administered and assessed no significant increases in physical activity (p=0.87).

Within a pre-test post-test single group intervention, Kroese et al. (2013) assessed physical activity (Schuit et al., 1997) and reported initial improvements in physical activity but did not report any mean scores.

3.5.4.3.2 Self-monitoring of blood glucose.

Only one RCT measured blood glucose monitoring and found no significant increases following a computer guided goal-setting intervention (Glasgow et al. 2004).

3.5.5 Behaviour Change Techniques.

3.5.5.1 Presence of BCTs.

The frequency of the different BCTs used across the interventions is shown in Table 2. ‘Goal-setting (behaviour)’ was most frequently used across interventions and was identified in 10 of the 12 interventions (83.3%). The frequency of use of each BCT within each intervention when included was also calculated. ‘Review outcome goals’ was used most frequently per intervention, and was coded an average of 2.6 times within each intervention. Full detail on BCTs coded within individual studies can be found in Appendix V.

Table 3.2.

Frequencies of 'goals and planning' and 'feedback and monitoring' BCTs used in the interventions

BCT	N	% of included interventions using BCT	Average number of times BCT is used within each intervention
1.1. Goal-setting (behavior)	10	83.3%	1
1.2. Problem solving	8	66.7%	2
1.4. Action planning	7	58.3%	1.3
1.7. Review outcome goal(s)	5	41.7%	2.6
1.5. Review behavior goal(s)	4	33.3%	2.5
2.6. Biofeedback	4	33.3%	1
1.3. Goal-setting (outcome)	3	25%	1
2.3. Self-monitoring of behaviour	2	16.6%	1

Note. BCTs were not included in the table if they were not coded as present at all (1.6: 'Discrepancy between current behaviour and goal';1.8: 'Behavioural contract';1.9: 'Commitment'; 2.1: 'Monitoring of behaviour by others without feedback'; 2.2. 'Feedback on behaviour'; 2.4: 'Self-monitoring of outcome(s) of behaviour'; 2.5: 'Monitoring of outcome(s) of behavior without feedback'; 2.7: 'Feedback on outcome(s) of behaviour')

3.5.5.2 Number of BCTs and Effect Size.

The relationship between the total number of BCTs coded within an intervention and the level of change of the primary outcome HbA1c, was tested and was found non-significant for the randomised control trials ($r = 0.45$, $p = .45$) and for the single group design studies ($r = 0.98$, $p = .11$). While the correlation for the single group designs was quite high, this may not have been significant due to the small number of studies.

3.5.5.3 Relative Effectiveness of Individual BCTs.

A subgroup analysis of which BCTs were associated with changes in diabetes related outcomes was not possible due to the small number of intervention studies identified.

3.6 Discussion

The aim of this review was to assess the effectiveness of goal-setting focussed behavioural change interventions on clinical, health, psychosocial or behavioural outcomes in people with diabetes. Furthermore, it set out to identify which "Goals and planning" and "Feedback and monitoring" BCTs are most frequently used in these interventions and which are most effective in improving outcomes. To identify all relevant studies, goal-setting interventions using various designs and targeting a wide range of diabetes related outcomes were included. Following a systematic screening process, we included 12 intervention studies, described in 14 papers. Due to the heterogeneity of designs and measures, it was not feasible to pool effect sizes for all studies and outcomes.

A small meta-analysis of RCTs found a main effect for HbA1c as a result of goal-setting focussed interventions, which suggests that goal-setting interventions could be a beneficial strategy for improving glycaemic control. While these results are encouraging, the low number of studies included in this analysis does imply that these results should be approached as tentative. Furthermore, caution should be taken in regards to the clinical significance of these findings as the average decrease in HbA1C was quite low. Results taken from single group pre-test post-test studies were less conclusive as only 30 percent of these studies showed a significant decrease in HbA1c. However, evidence taken from single group designs tends to be more sensitive to biases, and should therefore be approached with more care. In regards to body weight, meta-

analysis with a small number of studies found no significant changes in body weight following goal-setting focussed interventions.

In regard to psychosocial health outcomes, five studies measured levels of self-efficacy. Self-efficacy has been identified as an important construct in behaviour change and goal-setting literature, as high levels of self-efficacy predicting higher levels of engagement in behavioural change, including self-management behaviours (Strecher et al.,1995). In our review, we were unable to draw strong conclusions around the importance of self-efficacy, as four interventions found significant increases in self-efficacy versus one study that did not. DeWalt et al. (2009) & Wallace et al. (2009) found the highest improvements in self-efficacy. The intervention described in these articles reported that 93 percent of patients achieved at least one of their goals during the intervention. These high levels of goal-achievement may have led to a stronger rise in self-efficacy results, as goal-setting theory suggests that goal-achievement leads to increased self-efficacy (Strecher et al.,1995). In regards to quality of life, no strong conclusions about the direction of effect could be drawn from these finding due to the low number of studies reporting quality of life.

The small number of studies reporting behavioural outcomes limited the ability to draw conclusions about the effects of goal-setting interventions on behavioural outcomes in people with diabetes.

All interventions were coded using the BCTTv1 (Michie et al.,2013), with ‘Goal-setting (behaviour)’ emerging as the most frequently reported BCT. This strategy includes setting or agreeing a goal with a patient in terms of behaviour to be achieved. The high implementation of this BCT could possibly have contributed to the overall positive effects on HbA1C levels. Goal-setting theory suggests that specific behavioural goals such as ‘check blood sugar before every meal for 2 weeks’ are more likely to be

achieved then vague long term outcome goals such as ‘reduce HbA1C levels’. Breaking down complex and long term diabetes goals into simpler short term sub-goals could possibly be a useful strategy for health professionals to help patients reach their diabetic goals (Strecher et al.,1995).

‘Feedback and monitoring’ techniques were less frequently included in interventions. Only two of the 12 studies incorporated a ‘feedback and monitoring’ BCT within the intervention. This was surprising as goal-setting theory suggest feedback loops can have a significant impact on goal-setting as an active ingredient in health interventions (Latham, 2003). In fact, a systematic review of implementation interventions for diabetes care, that is currently under review (Presseau, 2016), suggest that ‘feedback on outcomes of behaviour’ seemed to be the most powerful BCT to reduce HbA1C in people with diabetes. Implementing higher levels of ‘feedback and monitoring’ techniques could possibly help improve goal-achievement and could increase the chance of intervention success (Locke & Latham, 2002; Strecher et al.,1995).

Our findings indicate that interventions did not necessarily lead to better outcomes in this context if more BCTs were implemented. This finding is not uncommon in behavioural change literature. Previous research has suggested that there may be more differences in the quality of intervention delivery when the number of BCTs increases, which could increase the possibility of inconsistent effects (Michie, Jochelson, Markham, & Bridle, 2009).

3.6.1 Limitations.

While this review was systematically conducted, it is not without its limitations. We lacked sufficient data to calculate pooled effect sizes for all outcome measures. Furthermore, due to the small number of studies included in the meta-analyses, caution

must be applied when generalising these findings. It seems that while many studies incorporate goal-setting techniques within complex interventions (Presseau et al., 2015), only few use goal-setting as their primary intervention strategy. Therefore, more research is needed to create stronger and more robust effectiveness measures. Additionally, no grey literature was included within this review. As indicated by a significant risk of publication bias, it is possible that more studies have been conducted without being published. Therefore, future reviews should aim to include grey literature to create a more complete overview of goal-setting interventions.

A set of limitations lie within the BCT analyses. In this review, we were limited in our coding by the amount of information provided in papers or given by authors. As has been frequently observed in the behaviour change literature (Riley et al., 2008), studies did not always report the content of the interventions in sufficient detail (de Bruin, Viechtbauer, Hospers, Schaalma, & Kok, 2009). This could have resulted in some BCT coding difficulties and it is possible that, in some cases, the content of studies has not been accurately captured. Furthermore, studies that reported usual care as a control condition provided limited information on what this entailed. Therefore, some forms of goal-setting could have taken place within usual care and could therefore affect the reliability of the data.

Additionally, the fidelity of BCT delivery was not discussed within the included studies. Addressing fidelity is key to ensuring that interventions are delivered as intended (Bellg et al., 2004). However, to properly code such information, observation of the intervention would often be needed (Lorencatto, West, Christopherson, & Michie, 2013).

Our BCT coding approach coded for the presence and frequency of techniques but not for the intensity or quality with which they were delivered or implemented.

While the BCTTv1 is a useful and widely used tool for coding active ingredients of interventions content, some research criticises the taxonomy for only capturing a segment of what theory states about active content of interventions (De Bruin, Crutzen, & Peters, 2015). In an alternative taxonomy of behaviour change methods, Kok et al. (2016) argue that when implementing a behavioural change method, certain conditions must be satisfied in practical application for a method to be effective. For example, Kok et al. (2016) state that goal-setting can be an effective method for behaviour change, but only if a goal is relevant and challenging yet still achievable. If people chose goals that are outside of these 'theoretical parameters', this could impact on effectiveness. The BCTTv1 disregards whether theoretical parameters are met within an intervention to ensure optimal use of a BCT (De Bruin, Viechtbauer, Hospers, Schaalma, & Kok, 2009). However, retrospectively coding this information would require extremely detailed and systematic intervention descriptions, which is often the exception rather than the rule. Within this review, the included studies provided very little information around the types of goals that were set and their individual difficulty levels. While future research could benefit from assessing the quality with which BCTs are applied, it appears that the BCTTv1 is currently the most appropriate tool for coding intervention content.

Despite our best efforts to screen studies that focussed solely on goal-setting techniques in their interventions, most studies did not rely exclusively of goal-setting techniques. Additional BCTs appeared in several studies. Therefore, the full range of effects could have been spread over these additional BCTs.

This study set out to not only assess overall effectiveness, but to identify which specific BCTs were most effective in improving diabetes related outcomes. The paucity of intervention studies meant that this analysis was limited. A higher number of RCT

studies on goal-setting interventions in diabetes management are needed to draw firm conclusions.

Finally, despite aiming to include studies targeting people with T2DM and T1DM, only one of the interventions included people with T1DM in their sample. This indicates a lack of research on goal-setting interventions targeting T1DM. While many similarities exist between self-management behaviours for T1DM and T2DM, there are also substantial differences in the management of both illnesses (Ahlqvist et al., 2018). These differences in illness management could lead to the development of different types of goals in behaviour change interventions, which could have an impact on the generalisability of the findings. To create a better understanding of the effectiveness of goal-setting strategies across different types of diabetes, more research is needed to assess the effectiveness of goal-setting interventions in T1DM.

3.6.2 Conclusion and practical implications.

The implementation of goal-setting techniques within diabetes self-management programmes is widely recommended (Haas et al., 2013). However, in practice the empirical evidence of whether and when this is effective is lacking (Miller & Bauman, 2014). To our knowledge, this review is the first to systemically assess the effectiveness of goal-setting focussed interventions aimed at improving diabetes outcomes and to provide valuable information on which BCTs are most commonly used within these interventions. A meta-analysis documented modest but significant post-intervention improvements in HbA1C outcomes. The relatively small numbers of included studies and the risk of potential bias across studies do suggest that more research is needed to further explore goal-setting and planning BCTs in diabetes self-management. Furthermore, future research should focus on examining if the use of more feedback and monitoring BCTs alongside goal-setting BCTs increases intervention effectiveness.

Our outcomes should be approached as tentative due to the small number of studies included in the analysis. However, a meta-analysis did reveal a clear pattern of decreasing HbA1c levels across the included goal-setting interventions. This indicates that implementing goal-setting techniques within future diabetes self-management interventions appears to be advisable. However, it is important to highlight that goal-setting is a complex process and if implemented, should be implemented properly using a theoretical base (Locke & Latham, 2002). Using theories such as goal-setting theory to inform appropriate application of BCTs and guide intervention development is recommended as it is suggested to increase the likelihood of successful behaviour change (Michie et al.,2011; Kok et al., 2016).

3.7 Disclosure Statement

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4. Study 2: Goal-setting in DAFNE: A Content and Fidelity Exploration of the Goal-Setting Component of a Type 1, Diabetes Self-Management Programme.

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4.1 Abstract

Diabetes self-management education (DSME) has been evolving into person-centred programmes that typically implement behaviour change components such as goal-setting. However, DSME has inconsistent effects on long term health-outcomes. Issues with implementation fidelity, the extent to which interventions are implemented as intended, within behaviour change components may contribute to these inconsistencies. This study was the first to explore how goal-setting is addressed and delivered in a widely implemented T1DM DSME-programme, by systematically assessing content and implementation fidelity of the goal-setting component of the "Dose Adjustment for Normal Eating" (DAFNE) programme. The manual of DAFNE's goal-setting component was coded using a standardised list of behaviour change techniques (BCTs). Fidelity was assessed according to session, educator and BCT by observing and audio-recording 20 DAFNE goal-setting sessions and comparing the number of manual-specified BCTs, with BCTs delivered in practice. The data revealed that on average, 57.8% (SD 23.1; range: 17.2% to 87.5%) of the manual-specified BCTs

were delivered in practice with large variation across educators, session-type and BCTs. The study highlighted that behaviour change content is not consistently delivered as outlined in DSME-programme manuals. Therefore, even within highly established and standardised education programmes, routine procedures for monitoring implementation fidelity and continuous support for educators seems advisable.

KEY WORDS: Implementation fidelity, goal-setting, diabetes self-management education, DAFNE, Dose Adjustment For Normal Eating.

4.2 Introduction

The prevalence of diabetes is increasing across all age groups (Geiss et al., 2014) and is expected to rise to a prevalence of 10.4% in adults by 2040 (Ogurtsova et al., 2017). One of the global responses to this rise has been an increase in diabetes self-management education (DSME) programme development (Powers et al., 2017; Schinckus et al., 2014). DSME-programmes are often group based structured courses aimed at improving knowledge, skills and abilities for diabetes self-management and hereby empowering people with diabetes to live healthily and manage their diabetes better (Forde et al., 2009). DSME-programmes tend to follow written curriculums reflecting current evidence and practice guidelines, and are typically delivered by medically trained educators (Funnell et al., 2009).

Along with the increase in self-management interventions and education programmes, a growing area of research focusses on how effective these programmes are (Chrvala et al., 2016), and how well they are implemented (Schinckus et al., 2014). Implementation fidelity has been described as the extent to which an intervention, programme or treatment is implemented as originally intended (Bellg et al., 2004). A large body of evidence shows that face-to-face interventions are often not delivered as specified in their intervention manuals (Bellg et al., 2004; Campbell et al., 2000). This

variation in intervention delivery could affect outcomes and treatment effectiveness (Bellg et al., 2004). Addressing implementation fidelity within intervention research is becoming increasingly important; both the extension of the CONSORT-statement for non-pharmacological treatments (Boutron et al., 2008) and the Medical Research Council Guidance on intervention development and evaluation (Craig & Petticrew, 2013) emphasise the importance of monitoring and reporting implementation fidelity.

With the increasing importance of addressing implementation fidelity within research, an intensifying debate surrounds the balance between fidelity of programme delivery and adaptation of the programme to the local context. Arguments have been made that the modification of program content, to address the needs of a specific participant group, is essential (Borrelli, 2011; Hawe, Shiell, & Riley, 2004; Kemp, 2016). While a certain level of flexibility to address individual needs could be beneficial (Hawe et al., 2004), implementation fidelity is crucial for internal validity and determining the degree to which an intervention is the main mechanism responsible for observed changes (Bellg et al., 2004). Significant variety in delivery of an intervention could represent a potential factor in outcome variations. Furthermore, assuring content and quality consistency of an intervention or treatment programme across delivery is of ethical importance to ensure that participants are receiving equal treatment (Seedhouse, 2008). Additionally, an increasing number of studies have demonstrated that the level of fidelity with which interventions are implemented can affect their success rates (Carroll et al., 2007; Elliott & Mihalic, 2004; Mihalic, 2004), suggesting that high implementation fidelity is related to positive outcomes (Hasson et al., 2012; Keith et al., 2010).

Although the importance of examining fidelity is widely recognised, research shows that it is often not assessed within intervention research (Bellg et al., 2004;

Schinckus et al., 2014). Furthermore, fidelity research mainly focuses on evaluating new interventions, as opposed to assessing the fidelity with which interventions and programmes are delivered when subsequently implemented in practice (Schinckus et al., 2014). This was highlighted in a recent systematic review by Schinckus et al. (2014), which set out to clarify how implementation fidelity is currently operationalized and assessed within DSME-programmes. Schinckus et al. (2014) found that very few studies addressed the issue of fidelity, and when it was mentioned, the information provided was often incomplete. In particular, details about the conceptualization and measurement of implementation fidelity were generally missing. It seems that while scientific movements are pushing towards higher levels of implementation fidelity measures, it is still a rarity that fidelity is assessed within interventions or education programmes delivered in practice.

A good example of a structured DSME-programme is the ‘Dose Adjustment for Normal Eating’ (DAFNE) programme (DAFNE study group, 2002). DAFNE has been extensively implemented and has become part of routine diabetes care within the United Kingdom, Ireland, Australia and several other countries (DAFNE U.K., 2017). DAFNE is a five day DSME-programme that covers all aspects of living with type-1 diabetes (T1DM). The programme particularly emphasises the key skill of matching insulin to estimated carbohydrate intake (DAFNE study group, 2002). Trials have shown that DAFNE graduates tend to have greater diabetes knowledge and show long-term improvements in quality of life (Cooke, Bond, Lawton, Rankin, Heller, Clark, Speight, et al., 2013; Dinneen et al., 2009; Speight et al., 2010). However, the long-term benefits for medical outcomes such as average blood-glucose levels (HbA1c) tend to be more modest (Speight et al., 2010). Longitudinal research reveals that initial improvements in HbA1c, while statistically significant, tend to decrease over subsequent years (Cooke,

Bond, Lawton, Rankin, Heller, Clark, & Speight, 2013; Gunn & Mansell, 2012; Speight et al., 2010). It seems that even though DAFNE has become an established programme within diabetes care, it does not always help participants incorporate key habitual self-management practices into their lives on a long-term basis.

DSME-programmes like DAFNE have been evolving significantly in recent years. An increased emphasis is put on person-centred and collaborative approaches to education (Funnell et al., 2007) and the implementation of behaviour change components such as goal-setting and action-planning is increasing (Funnell et al., 2007). Particularly goal-setting has been identified as a core component present across DSME-programmes (Grant et al., 2013). Despite the wide implementation of goal-setting within DSME, a recent research prioritisation exercise, conducted with diabetes stakeholders, identified ‘goal-setting with patients’ as a priority research focus for behavioural research in diabetes (Mc Sharry et al., 2016), indicating that stakeholders felt that this area requires further exploration.

Goal-setting is one of the key components of DAFNE (Oliver & Thompson, 2009). However, in evaluating the effectiveness of DAFNE, Speight et al. (2010) highlighted that DAFNE needs to be modified and that more attention must be paid to components that are likely to contribute to successful behaviour change. Goal-setting, problem-solving and planning strategies are seen as important efforts in enhancing patient autonomy, and automating future responses to internal and external ques (Hollands et al., 2016). Therefore, accurate implementation and delivery of these components could contribute to long-term behaviour change (Epton et al., 2017; Strecher et al., 1995). Exploring how goal-setting is addressed within DSME-programmes as DAFNE, and exploring its levels of implementation fidelity, therefore appears necessary and could provide insights into the long-term adherence to DAFNE-

principles, which are often reported as suboptimal (Gunn & Mansell, 2012; Speight et al., 2010). Additionally, it can provide insights into the level of support and monitoring that is required for educators delivering these behaviour change elements of DSME-programmes.

Within the field of behavioural science, recent movements propose that intervention content should be specified in terms of Behaviour Change Techniques (BCTs) to improve clarity around the mechanisms by which behaviour is suggested to change (Craig & Petticrew, 2013; Michie et al., 2013). Michie et al. (2013) initiated this movement by developing a comprehensive taxonomy, or list, of BCTs. BCTs are proposed to be the smallest components of interventions that can bring about change (Michie et al., 2013). The taxonomy consists of 93 BCTs clustered into 16 groups. Each BCT has a clear label and description, and holds specified criteria for its usage or operationalisation. Describing intervention content in terms of BCTs has been demonstrated as a feasible classification method and is becoming increasingly common within behaviour change research (Lorencatto et al., 2013; Michie, Abraham, et al., 2009; Michie et al., 2013).

Within the area of smoking cessation, recent studies utilised BCT taxonomies to describe intervention content, and systematically assess implementation fidelity by comparing content of treatment-manuals with the transcripts of corresponding smoking cessation support sessions (Lorencatto et al., 2014; Lorencatto et al., 2013). Using the BCT-taxonomy to code the content of DSME-programmes is a novel but necessary approach, as standardisation of intervention content description becomes increasingly important (Michie et al., 2013). Furthermore, this approach offers a systematic method to assess fidelity of delivery of the goal-setting component of DAFNE.

This study therefore aims to explore the content and the fidelity of delivery of

the goal-setting component of DAFNE. Specific objectives are to specify the goal-setting component's content in terms of BCTs (Michie et al., 2013); to assess overall fidelity of delivery of the goal-setting sessions, using a checklist of manual-identified BCTs; to assess variation in fidelity according to educator, session type, and specific BCTs (Lorencatto et al., 2013); and to identify implemented BCTs not specified within the intervention-manual.

4.3 Method

4.3.1 Study design.

This study followed a descriptive and observational design in which content from the manual of the goal-setting component of DAFNE was specified in terms of BCTs and fidelity of delivery was assessed by comparing this content, with corresponding observations and transcripts of audio-recorded DAFNE sessions.

4.3.2 Study sample.

Seven diabetes clinics offer DAFNE within Ireland, of which three were included in this study. Clinics were selected based on number of DAFNE-programmes delivered within the study time, and geographic accessibility.

Participants in this study were defined as DAFNE educators and DAFNE participants. Educators were trained staff (dieticians or diabetes nurses) delivering DAFNE. A total of six female educators were recruited, four of whom actively delivered the goal-setting component and two educators who took an assisting role in these sessions. Characteristics of the DAFNE educators are highlighted in Table 4.1 DAFNE participants were people with T1DM, attending an observed DAFNE-course. A total of 74 DAFNE agreed to take part in the study by consenting to an audio-recording.

Table 4.1.

Characteristics of DAFNE educators

n = 6

Characteristics	
Median age, years (range)	44.5 (30-52)
Female, n (%)	6 (100%)
Median years of experience as DAFNE educator (range)	7 (1-11)
Occupational background	
Nursing, n	2
Dietician, n	4
Role in goal-setting component	
Lead delivery	4
Assisting in delivery	2

4.3.3 Materials.

4.3.3.1 DAFNE goal-setting component.

The DAFNE-programme is delivered over five consecutive days and involves 38 hours of structured education. The course content is spread over 21 sessions, with each day consisting of a number of sessions. DAFNE is delivered by a diabetes specialist nurse, a dietitian and a doctor, all of whom have undergone training in delivering the DAFNE-curriculum. Goal-setting is briefly mentioned in an introduction session on day one, but is fully addressed in two sessions later in the week. Within the first goal-setting session, DAFNE participants are taught the principles of goal-setting and behaviour change. They follow up on this in the second session, by writing down a goal and developing an action-plan. In all included centres, the dietician took responsibility for the delivery of both goal-setting sessions.

4.3.3.2 DAFNE programme –manuals.

The manuals and workbook of the DAFNE sessions along with study approval were obtained from the DAFNE office UK. The manuals are guidance documents for DAFNE educators, providing a written plan specifying the procedures to be followed in delivering the DAFNE sessions. The DAFNE workbook is a document for participants containing instruction and exercises relating to particular DAFNE topics.

4.3.4 Procedure.

4.3.4.1 BCT coding of the DAFNE manuals.

Two researchers independently coded the two goal-setting sessions in the DAFNE-manual and workbook using the BCTTv1 (Michie et al., 2013). Both reviewers had completed BCT-coding training. Agreement was registered if both reviewers identified the same BCT within a section of text. Disagreement was registered if one reviewer identified a BCT while the other reviewer had not identified this BCT or had identified a different BCT. Discrepancies were resolved through discussion. The identified BCTs, and details their manual specified delivery by the educators, were put into two fidelity checklists, each representing one goal-setting session (due to copyright, the fidelity checklists cannot be made available for publication).

4.3.4.2 Observation/ audio-recordings.

DAFNE sessions were observed and audio-recorded between October 2016 and October 2017. Informed consent for audio-recordings was obtained from the educators delivering the DAFNE-programme, and the participants attending the course. If consent was obtained from all parties, the researcher would directly observe the goal-setting sessions and audio-record the sessions simultaneously. If any participants did not

consent to an audio-recording, sessions were observed only and rated for fidelity during the observation.

A total of 20 individual goal-setting sessions across a total of ten DAFNE-courses were observed. Sixteen sessions were audio-recorded using a discrete recording device. All audio-recordings were transcribed verbatim by MF and all identifying information was removed. Four sessions were observed without an audio-recording taking place as consent for audio-recording was not obtained from all parties.

4.3.5 Analysis.

4.3.5.1 BCT coding.

When coding the manuals using the BCTTv1 (Michie et al., 2013), inter-rater reliability was calculated between the coders using Cohen's kappa (Cohen, 1968).

4.3.5.2 Fidelity and delivery characteristics.

Using a checklist of manual-specified BCTs, fidelity of delivery for both DAFNE goal-setting sessions was measured by comparing the BCTs coded within the DAFNE-manual and workbook of each session and BCTs delivered in practice during the observations of these sessions. To address quality of BCTs delivery, and to take into account that BCTs may be delivered wholly or in part (Michie et al., 2018) manual-specified BCTs were rated as delivered (1; delivered in full, beyond all reasonable doubt), partly delivered (0.5; delivered in all probability but evidence not clear, or delivered in part) or not delivered (0). This coding scheme followed examples from previous work (Keogh et al., 2018; Wood et al., 2015),

A total score was calculated per session by adding the scores of all BCTs. 20% of the transcripts were double rated by two independent researchers and inter-rater

reliability was calculated using Cohen's kappa (Cohen, 1968); discrepancies were resolved through discussion.

Overall fidelity of delivery was calculated as an average score across all goal-setting sessions. Variation in fidelity was calculated according to educator and session type by comparing average fidelity scores. In addition, we assessed fidelity of delivery per type of BCT (Michie et al., 2013), by dividing the amount of times each BCT was delivered across all observations, by the amount of times each BCT was expected to be delivered across all observations if fidelity was 100%. Fidelity scores were expressed as a percentage.

Session duration was documented for each observation, and average duration was calculated. Pearson's correlations were completed to explore the relationship between fidelity scores and session-duration (Sedgwick, 2012).

The transcripts from the audio-recorded sessions were coded for additional BCTs not included within the manuals.

4.4 Results

4.4.1 Content of the sessions (BCT-analysis).

The DAFNE goal-setting sessions were designed to promote goal-setting and action-planning behaviours within the sessions, and goal-pursuing behaviours after DAFNE. As highlighted in Table 4.2, 13 different BCTs (Michie et al., 2013) were identified within the intervention manuals and workbook across both DAFNE goal-setting sessions (10 within session one, 8 within session two, 5 BCTs were present within both sessions). These 13 BCTs were used/operationalised a total of 41 times throughout the sessions. Some BCTs, such as 'Credible source' were operationalised

several times throughout the sessions, in different ways. There was good interrater agreement between coders (κ = 0.77) (Cohen, 1968; Landis & Koch, 1977).

Table 4.2.

Content of the goal-setting sessions (BCT-coding)

Behaviour Change Technique (Michie et al., 2013)	**Number of times BCT was coded in the manual**		
	Session 1	Session 2	Total
1.1 Goal-setting (behaviour)	1	0	1
1.2 Problem solving	4	2	6
1.3 Goal-setting (outcome)	1	3	4
1.4 Action-planning	7	5	12
3.1 Social support (unspecified)	2	1	3
3.2 Social support (practical)	0	1	1
4.1 Instruction on how to perform the behaviour	1	1	2
6.1 Demonstration of the behaviour	0	1	1
8.1 Behavioural practice/ rehearsal	0	1	1
9.1 Credible source	4	0	4
10.6 Non-specific incentive	1	0	1
10.7 Self-incentive	1	0	1
15.3 Focus on past success	4	0	4
Total	26	15	41

BCTs coded within the manual and workbook for session one and session two, the number of times each BCT was coded within each session and the total number of times each BCT was coded across both sessions within the DAFNE course.

4.4.2 Fidelity and delivery characteristics.

4.4.2.1 Reliability of fidelity assessment.

A good inter-rater reliability (Landis & Koch, 1977) was calculated for fidelity of delivery assessment ($\kappa = 0.79$)

4.4.2.2 Overall fidelity and fidelity per session type.

Across 20 goal-setting sessions, the average percentage of manual-specified BCTs that was delivered in practice was 57.8% (SD 23.1; range: 17.2% to 87.5%). An average of 40.1% (SD 16.9; range 17.2% to 68.2%) of BCTs were delivered within session one, and an average of 75.36% (SD 12.4; range 58.3% to 87.5%) within session two (see Appendix IX for more details).

4.4.2.3 Fidelity per BCT.

On average, the fidelity score per type of BCT was 51.5% (SD 26.6). Table 4.3 shows fidelity scores for each BCT across ten observed DAFNE-courses (20 goal-setting sessions). The fidelity scores ranged widely across BCTs with ‘Behavioural practice/ rehearsal’ having perfect fidelity of 100% and ‘Goal-setting (behaviour)’ having very low fidelity of 5%.

Table 4.3.

Fidelity per BCT

BCT (Michie et al., 2013)	**Total number of times BCT coded in manuals (across both goal-setting sessions)**	**Total number of times BCT expected to be delivered for 100% fidelity (for 10 observed courses)**	**Total no. of times BCT delivered**	**Fidelity of delivery score in %**
1.1 Goal-setting (behaviour)	1	10	0.5	5%
1.2 Problem solving	6	60	39.5	65.8%
1.3 Goal-setting (outcome)	4	40	30.5	76.3%
1.4 Action-planning	12	120	78.5	65.4%
3.1 Social support (unspecified)	3	30	16.5	55%
3.2 Social support (practical)	1	10	2.5	25%
4.1 Instruction on how to perform the behaviour	2	20	8.5	42.5%
6.1 Demonstration of the behaviour	1	10	4.5	45%
8.1 Behavioural practice/ rehearsal	1	10	10	100%
9.1 Credible source	4	40	26.5	66.3%
10.6 Non-specific incentive	1	10	2.5	25%
10.7 Self-incentive	1	10	2.5	25%
15.3 Focus on past success	4	40	30	75%
Average fidelity score				51.6%

List of BCTs coded in manuals across both session types, number of times the BCT was expected, delivered and fidelity of delivery score across 10 observed courses.

4.4.2.4 Fidelity per educator.

Each educator delivered an average of 5 sessions (range: 4 to 8). On average, each educator delivered an average of 56.2% of the proportion of manual-specified BCTs (range 41.95% to 64%).

4.4.2.5 Fidelity as a function of session duration.

The average duration of session one was 19.67 minutes (SD: 9.10; range 9.50 to 33.34). The average duration of session two was 24.55 minutes (SD: 8.42; range 19.4 to 40.25). No significant correlations were found between session duration and the amount of manual-specified BCTs delivered in session one (r= -0.07, *p*= 0.837), session two (r= -0.515, *p*= 0.128), or across both sessions (r= -0.069, *p*= 0.773).

4.4.2.6 Delivery of BCTs not included in the manual (i.e. additional content).

On average, each session contained 0.61 additional BCTs that were not identified in the manual (SD: .70, range 0 to 2). The following BCTs were identified: 'Information about emotional consequences' (n=2), 'Feedback on behaviour' (n=5), 'Information about health consequences' (n= 1), 'Pharmacological support' (n=2) and 'Prompts/cues' (n=1) (Michie et al., 2013).

4.5 Discussion

This study aimed to explore the content and fidelity of delivery of the goal-setting component of the DAFNE-programme (DAFNE study group, 2002). With high agreement between coders, this study was the first to code content of the DAFNE programme-manual using a standardised list of techniques, the BCTTv1 (Michie et al., 2013). This allowed for the specification of the active ingredients of the goal-setting component of DAFNE. The study was also the first to rigorously assess fidelity of

delivery in a diabetes self-management programme by comparing manual-specified BCTs with BCTs delivered in practice.

Across both goal-setting sessions, 13 BCTs were identified within the DAFNE-manuals and workbook, with ‘action-planning’ most frequently coded. The majority of included BCTs came from the ‘Goals and planning’ BCT-cluster of the BCTTv1 and corresponded well with elements of goal-setting theory (Locke & Latham, 2002). However, there was limited inclusion of feedback and monitoring techniques. This is regularly seen among goal-setting interventions targeting diabetes outcomes (Fredrix, McSharry, Flannery, Dinneen, & Byrne, 2018). However this is not consistent with goal-setting theory, suggesting that goal-setting practices can strongly benefit from feedback-loops (Strecher et al., 1995). Not providing patients with feedback on their set goals or on their performance on a regular basis could have a significant impact on the effectiveness of goal-setting techniques within the programme.

BCT coding of DAFNE-manuals and workbooks provided a systematic structure for identifying goal-setting content, and allowed for the assessment of implementation fidelity by observing and audio-recording BCTs delivered during goal-setting sessions. We found that on average 57.8 percent of manual-specified BCTs were delivered in practice. Published guidance and recommendations have categorised fidelity scores over 80 percent as ‘high’, with scores less than 50 percent described as ‘low’ fidelity (Borrelli, 2011; Lorencatto et al., 2013). This indicates that overall fidelity scores were close to being classified as low. These levels of fidelity are not unusual and are consistent with implementation fidelity outcomes within other behaviour change interventions (Borrelli et al., 2005; Griffin et al., 2009; Hardeman et al., 2008; Lorencatto et al., 2013; Schinckus et al., 2014; Whittemore et al., 2010). However, this study revealed relatively high levels of variation in fidelity scores across sessions,

ranging from 17.2 to 87.5 percent. High variation in fidelity across sites and educators suggests lack of standardisation and the potential for variation depending on which DAFNE-programme patients attend. These variations in implementation fidelity within this behaviour change driven component, could contribute to observed differences in participant's achievement of long-term diabetes goals following DAFNE, as patients may not receive the same intervention.

In comparing averaged fidelity scores per session-type, we identified significantly higher levels of fidelity for the second goal-setting session. This difference in fidelity is most likely attributable to the fact that session two, the goal-generating and action-planning session, was mostly workbook based. Workbooks tend to provide a clear structure to a session, making fidelity of delivery more attainable. While other research has shown that incorporating a workbook can be beneficial for fidelity levels, not all content is equally suitable for the use of a workbook (Bond, Drake, McHugo, Rapp, & Whitley, 2009).

Consistent with previous implementation fidelity research (Lorencatto et al., 2014; Lorencatto et al., 2013; Sweeney-Magee et al., 2016), we also found large variety in fidelity scores between types of BCTs, ranging from perfect fidelity in 'Behavioural practice/ rehearsal' to very low fidelity in 'Goal-setting (behaviour)'. Understanding why some BCTs are delivered with greater fidelity is important, especially as the BCT delivered least consistently, 'goal-setting behaviour', is theorised to be more effective then setting goals in terms of outcomes, as behaviours are more directly under people's control and are more strongly related to concentration, effort and persistence (Strecher et al., 1995).

With regards to session duration, the programme manual recommends a minimum of 30-45 minutes to be spent on each session. However, our data revealed that

some educators spend no more than ten minutes on individual sessions. Nevertheless, we found that duration was not significantly associated with fidelity of delivery. Therefore, it could be argued that time pressure was not a contributing factor to low levels of fidelity throughout the study.

Fidelity of delivery is key for internal validity and ensuring that programmes are delivered in a consistent manner. However, one of the main debates in the area of implementation exists around balancing fidelity of delivery and adaptation of programme content to a local context (Castro, Barrera, & Martinez, 2004; Kemp, 2016). DAFNE-educators spend a significant amount of time with the participants and will likely develop a sense of what participants require. Therefore, tailoring DAFNE content to fit the group's needs is not necessarily problematic and could even be encouraged at times. This study found that some educators deliver additional BCTs, such as providing detailed feedback, which could potentially be a welcome addition to the goal-setting sessions (Strecher et al., 1995). However, these BCTs are not manual-specified or used consistently across centres. Therefore, they form a threat to internal validity when assessing DAFNE's effectiveness.

Within previous work by Hawe et al. (2004), arguments are made for fidelity to be defined as the degree to which delivery fits with the theory or principles of the hypothesised change process. While these views could be beneficial in making programmes more adaptable, there is a level of knowledge required regarding the theory in question on the part of the educator. It is uncertain whether educators in programmes such as DAFNE have the requisite knowledge to apply the theory or principles of goal-setting and action-planning without specific guidance. To avoid drifting away from key-content, it seems advisable that adaptation should be proactive and planned within the intervention designs, by emphasising crucial BCTs or having pre-planned adaptation

guidelines (Castro et al., 2004). Further qualitative research exploring educator's views on fidelity and reasons for adaption could be of value in understanding fidelity levels and help plan for adaptions.

4.5.1 Limitations.

Because the area of implementation fidelity is relatively novel, limited guidelines are available concerning sample-size and power (Bellg et al., 2004). This study was limited by the availability of DAFNE-courses in Ireland. Therefore, our samples size was relatively small, which could limit the generalisability of our averaged findings. However, the high variety in fidelity scores should not be discarded easily.

In the fidelity assessment, we somewhat limited our findings by not fully assessing the quality with which BCTs were delivered. If the content of an intervention is delivered, but delivered poorly, this could affect the degree to which full implementation occurs. While this limitation has been flagged in previous implementation fidelity research (Lorencatto et al., 2014; Lorencatto et al., 2013; Sweeney-Magee et al., 2016), no clear guidelines have been developed around assessing quality of BCT delivery to date.

The educators in this study were aware that their sessions were being observed and audio-recorded. Therefore, demand characteristics could have influenced the fidelity levels, as educators may have attempted to improve their delivery. While these sessions may therefore not be representative of typical practice, the sessions are more likely to over-estimate rather than under-estimate fidelity scores.

Associations between fidelity and programme effectiveness were not assessed within this study. While previous research suggests that differences in fidelity could represent a potential factor in explaining variation in participants' outcomes (Bellg et

al., 2004; Ellis, Naar-King, Templin, Frey, & Cunningham, 2007), future research will have to explore this relationship further.

This study assesses the fidelity of delivery of the goal-setting component of DAFNE. While adherence to a programme-manual is of great importance, the National Institute of Health Behaviour Change Consortium's fidelity framework proposes that there are five fidelity dimensions: design, training, delivery and participant receipt and enactment (Bellg et al., 2004). This study focussed mostly on the design and delivery dimensions, as it assesses the content of the manuals and how well educators adhere to these manuals. While most implementation fidelity research is conducted in this manner, future research should attempt to assess fidelity across all dimensions. Assessing whether educators are properly trained to deliver the programme (training), the degree to which participants initially understand and engage with the programme (receipt) and apply content as intended in a real-life setting (enactment) should be addressed to create a more complete overview of fidelity (Bellg et al., 2004; Borrelli, 2011).

4.6 Conclusions

While the importance of examining fidelity is widely recognised, research shows that it is often not assessed or reported within intervention research (Carroll et al., 2007; Elliott & Mihalic, 2004; Hasson, Blomberg, & Dunér, 2012; Schinckus et al., 2014). Therefore, this study aimed to explore the content and fidelity of delivery of the goal-setting component of DAFNE. By utilising the BCTTv1 (Michie et al., 2013) as a tool to reliably identify programme content, and to quantify fidelity of delivery, this study provides an example of a systematic method to reliably assess fidelity within a DSME-programme. The results revealed that in practice, educators tended to deliver approximately half of the content of DAFNE's goal-setting component, with large

variations in fidelity existing between observations, educators, session-type and BCTs. Furthermore, additional BCTs were delivered in several sessions. This implies that patients can have different experiences depending on which DAFNE-course they attend. While this study does not asses the association between fidelity and programme effectiveness, previous research suggests that differences in fidelity could represent a potential factor in explaining variation in participants' achievement of long-term diabetes goals (Bellg et al., 2004; Ellis et al., 2007; Keith et al., 2010).

While intervention implementation training is often presented to providers at the beginning of a study or programme (Schinckus et al., 2014), there seems to be insufficient focus on monitoring and maintaining provider's skills as programmes continue to be implemented in practice (Bellg et al., 2004). The large variations in fidelity-scores within the behaviour change driven component of goal-setting implies that, even in established and standardised education programmes, continuous fidelity assessment is required. Furthermore, to improve fidelity within these types of programmes across the board, continuous support for educators seems advisable. Additionally, identifying priority BCT content, introducing workbooks or incorporating clearer guidelines on adaptation or personalisation within programme manuals could offer meaningful benefits to consistent programme delivery. This would add to the scientific rigour of the educational intervention's approach and in turn could improve treatment outcomes (Hasson et al., 2012; Keith et al., 2010; Schinckus et al., 2014) .

4.7 Declarations

4.7.1 Ethics approval.

This study received ethical approval from NUIG Research Ethics Committee, and from the Ethical Committees of the included Hospitals. Furthermore, this research has been approved by DAFNE-UK.

4.7.2 Funding.

This work was supported by a Health Research Board Research Leader Award 2013 (PI: Molly Byrne). The funding body had no role in the design of the study, collection, analysis, and interpretation of data or in writing the manuscript.

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5. Study 3: 'It's an important part, but I am not quite sure that it is working': Educators' perspectives on the implementation of goal-setting within the DAFNE Diabetes Structured Education programme.

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5.1 Novelty statement

- This study is the first to explore Diabetes Self-Management Education (DSME) educators' perspectives on the implementation of goal-setting and action-planning components within a DSME-programme.

- Educators are encouraged to embrace these behaviour change strategies to promote person-centred DSME. However, this study shows that while educators see value in goal-setting, many experience its delivery as challenging and would value additional training.

- Many educators questioned how well goal-setting currently fits within the DAFNE DSME-programme and are concerned about a lack of follow-up after DSME.

- Issues highlighted in this study should be addressed in DSME research, and could be targeted within DSME educators' training.

5.2 Abstract

Aims. Diabetes self-management education (DSME) programmes have evolved from information-provision based programmes, to person-centred and collaborative education programmes, typically implementing behaviour change components such as goal-setting and action-planning. While educators are crucial to DSME effectiveness, limited research has explored educators' views on delivering and operationalising these behaviour change components. Therefore, this study aimed to explore educators' perspectives on the implementation of goal-setting and action-planning strategies within a structured DSME-programme.

Methods. Ten semi-structured interviews were conducted with DSME educators delivering the 'Dose Adjustment for Normal Eating' (DAFNE) programme to people with T1DM throughout Ireland. A pre-designed topic-guide focussed on exploring educators' experiences of delivery and application and views on usefulness of goal-setting strategies, was utilised in all interviews. The interviews were recorded, transcribed and analysed using thematic-analysis.

Results. Five main themes were identified: 'People need a plan', discussing perspectives on goal-setting's value; 'the power of the group', highlighting the impact a group format has on goal-setting practices; 'diversity and individuality', discussing differences in DAFNE participants' and educators' engagement with goal-setting; 'goal-setting's fit', exploring perspectives on how well goal-setting fits within DSME and follow-up care; and 'feelings of inadequate psychological knowledge', addressing challenges experienced in the delivery of goal-setting components.

Conclusion. While educators saw benefits in the implementation of goal-setting and planning strategies within DSME, concerns about how well goal-setting currently fits within DSME and follow-up care were evident. Additionally, many educators experienced the delivery of goal-setting and action-planning strategies as challenging and would value additional training opportunities.

Key words:

Goal-setting, DAFNE, Diabetes self-management education, qualitative research, diabetes educators.

5.3 Introduction

The increasing diabetes prevalence has prompted a global rise in Diabetes Self-Management Education (DSME) (Saha et al., 2017). DSME-programmes are often group-based courses, aimed at improving knowledge, skills, and abilities for self-management. Structured DSME-programmes are typically delivered by trained educators and follow written curricula reflecting current evidence and practice guidelines (Chatterjee et al., 2017). The effects of DSME-programmes on health outcomes vary (Norris et al., 2002; Speight et al., 2010), and their long term effects on behaviour change tends to be modest (Norris et al., 2002). However, DSME-programmes are an efficient way to increase knowledge of self-management behaviours among people with diabetes and are recommended within international guidelines (American Diabetes Association, 2014).

DSME has evolved significantly in recent years. One vital change has been the increased emphasis on person-centred and collaborative approaches to education (Funnell et al., 2007), supplementing historical approaches which centred on the provision of information (Marteau et al., 2015). As part of this movement, DSME has

introduced behaviour change strategies such as goal-setting and action-planning (Funnell et al., 2007), with goal-setting being identified as a core component across DSME-programmes (Grant et al., 2013). Goal-setting, problem-solving and planning are seen as important strategies in enhancing people's autonomy, and automating future responses (Hollands et al., 2016), which can facilitate long-term behaviour change if implemented accurately (Epton et al., 2017; Latham, 2003).

However, incorporating behaviour change strategies within DSME-programmes, is not sufficient to ensure programme effectiveness (Anderson & Funnell, 2008). These strategies need to be carefully selected for the target audience and crucially, need to be implemented correctly (Michie et al., 2011). Therefore, knowledgeable, empathetic educators are key to the success of education programmes. DSME educators are typically HCPs responsible for translating manual-specified behaviour change content into practice. Their role is crucial in the success of DSME; the most intricately-designed programme will only be as effective as its least effective educator (Anderson & Funnell, 2008). However, limited research has explored educators' perspectives on operationalising behaviour change elements such as goal-setting. In support of HCPs' role in goal-setting, a recent research prioritisation involving key diabetes stakeholders identified 'goal-setting with patients' as a focus area for research in diabetes (Mc Sharry et al., 2016).

Engaging in person-centred goal-setting could be challenging for DSME educators and HCPs, as it requires a paradigm shift away from the traditional HCP-led model of diagnosis and treatment, to a more collaborative model in which people set personally-motivated goals (De Sutter et al., 2013). Arguably, a level of expertise around theoretical moderators of behaviour change principles is required when delivering components such as goal-setting (Epton et al., 2017; Kok et al., 2016).

However, limited research exists around DSME educators' understanding of these principles.

The 'Dose Adjustment for Normal Eating' (DAFNE) programme (DAFNE study group, 2002) is a widely implemented, five-day group-based structured DSME-programme, covering all aspects of living with T1DM. The programme is predominantly delivered by nurses and dieticians who attend a standardised training to deliver all components of the programme. Consistent with DSME guidelines (Funnell et al., 2009) DAFNE embraces goal-setting as one of its core components (Oliver & Thompson, 2009). While DAFNE tends to improve diabetes knowledge and quality of life in its graduates, the long-term effects on HbA1c tend to be more modest, implying that DAFNE does not always help participants instil self-management behaviours into their lives on a long-term basis (Speight et al., 2010). Research therefore recommends that more attention should be paid to factors within DAFNE that are likely to contribute to behaviour change (Speight et al., 2010). As goal-setting is widely-recommended for promoting behaviour change (Latham, 2003), further exploration of DAFNE's implementation of goal-setting is warranted.

DAFNE mainly addresses goal-setting within two group sessions in which theoretical-aspects of goal-setting setting and behaviour change are discussed, and participants set post-DAFNE-goals and develop action-plans to guide goal-achievement. A recent study (Fredrix, Byrne, Carr, & McSharry, 2018) looking at implementation fidelity, the extent to which an intervention or programme is delivered as originally intended, showed that in practice, DAFNE educators only deliver around half of the active content listed within the goal-setting component's programme-manual. Educators' judgments of a programme's acceptability could influence their interest and willingness to deliver a programme and implement it with fidelity (Reimers et al.,

1987). Exploring educators' views on the operationalising and implementation of goal-setting content could provide insights into fidelity levels, as well as guide DSME-programme optimisation.

Therefore, this study aims to explore educators' perspectives on the implementation of goal-setting strategies, supplemented by action-planning within the DAFNE-programme. Our objectives are to: explore how DAFNE educators experience the delivery and practical application of goal-setting and action-planning components within DAFNE; explore educators' views on the quality of these components; explore views on possible improvements to these components.

5.4 Methods

5.4.1 Design.

This study follows a qualitative design and is reported using the COnsolidated criteria for REporting Qualitative research (COREQ) checklist ((Tong et al., 2007); Appendix XII).

5.4.2 Recruitment and sample.

Eighteen DAFNE educators operate in Ireland across 7 centres. Due to this limited number, a convenience sampling strategy was utilised and educators were selected based on centre-participation and on willingness and availability to participate in the study. All educators operational in 4 different diabetes centres were approached (n=11). A total of 10 interviews were conducted; See table 5.1 for participant characteristics. Transcripts were reviewed after each interview, and thematic analysis was conducted with data from 8 interviews. Two additional interviews were conducted and analysed for further themes. Data saturation was reached after participant 8 as no new themes were identified in the final 2 interviews (Glaser et al., 1968).

Table 5.1.

Characteristics of interviewed DAFNE educators

n = 10

Characteristics	
Median age, years (range)	42.5 (30-52)
Female, n (%)	10 (100%)
Mean years of experience as DAFNE educator (range)	7 (1-13)
Occupational background	
Nursing, n (%)	5 (50%)
Dietician, n (%)	5 (50%)
Role in goal-setting component	
Lead delivery	5
Assisting in delivery	5

5.4.3 Data collection.

Semi-structured interviews were conducted between July 2017 and February 2018. A topic guide (Appendix XIII), following examples from other qualitative research, was utilised within all interviews. The guide was reviewed by a research team member with significant qualitative research experience (JMS) and piloted on the first participant to judge suitability. To be responsive to the data, an iterative approach was used (Ziebland & McPherson, 2006), and questions were added as new ideas emerged from early data exploration. Eight interviews were conducted face-to face and two via telephone. The interviews averaged 31 minutes (range 21-39), were audio-recorded with participants' consent, and transcribed in full.

5.4.4 Analysis.

The five stages of thematic analysis (TA; familiarization, generation of codes, searching for themes, reviewing themes and defining themes) outlined by Braun and Clarke (Braun & Clarke, 2013) were followed. Coding followed an inductive approach, with the main investigator (MF) creating codes reflecting the semantic content of the data. Codes were discussed with a second researcher (JMS). NVivo (version-11) was used to code transcripts and facilitate analyses and comparison of relationships between codes. In line with TA guidelines (Braun & Clarke, 2013), data pattern frequency, as well as level of meaning for answering the research questions, was taken into account in theme development. Themes were identified by MF and checked against original transcripts by JMS, to aid discussion and refinement.

5.5 Results

All educators referred to the practice of delivering DSME as rewarding and enjoyable. In exploring educators' perspectives on the implementation of goal-setting strategies supplemented by action-planning within DAFNE, five main themes and 9 sub-themes were identified (table 2). The themes are discussed in detail below, with quotes illustrating key points.

Table 5.2.

Main themes and subthemes

Theme 1	People need a plan
Theme 2	The power of the group
Subthemes	*2.1 Sharing is caring*
	2.2 Letting the group lead
	2.3 Group dynamics
Theme 3	Diversity and individuality
Subthemes	*3.1 It's not for everyone.*
	3.2. Diversity in educators
Theme 4	Goal-setting's fit
Subthemes	*2.1 Goal-setting's fit within DAFNE and DSME.*
	2.2 Goal-setting's fit within follow-up care
Theme 5	Feelings of inadequate psychological knowledge
Subthemes	*5.1 Less black and white.*
	5.2 Lack of training.

5.5.1 People need a plan.

Most educators embraced the importance of goal-setting and action-planning strategies within DSME. Providing people with large quantities of information, without developing a plan to guide behaviour change, was considered inadvisable.

> *"You can't just give people all this information and expect them to have a plan. […] They need to actually sit down and just write down what they think their plan is going to be (E3)."*

Some educators highlighted that goal-setting is key for protecting people against developing unrealistic goals and saw purpose in goal-setting "to try and hold back the ones that want it yesterday (E8)".

5.5.2 The power of the group.

DAFNE's group format and group dynamics were viewed as impacting the experience of delivering goal-setting and the degree to which participants benefit from and engage with these sessions.

5.5.2.1 Sharing is caring.

Learning from others by sharing experiences was considered beneficial: "People have struggled by themselves a lot. So being able to find a place to share safely is amazing (E9)". Discussing goals in a group was seen as making personally set goals more relevant and memorable.

> *"It's a benefit if they do talk about it, because it makes it more real maybe, instead of just writing it down (E2)."*

Educators highlighted that participants tend to be willing to share their goals but may not always be prompted to do so. Some considered this to be a limitation, as providing participants with feedback on goal-quality could be beneficial.

> *"They're really good at sharing. If you ask them a question, they'll all tell you. We just don't ask that question. It's actually something we should do (E3)."*

5.5.2.2 Letting the group lead.

When discussing fidelity, most educators spoke in support of the idea of adhering to goal-setting content as outlined in the DAFNE-manual, and felt that their fidelity levels were sufficient: "I'm not a word for word person, but certainly our lesson plan we would follow (E8)."

Many educators highlighted though, that 'letting the group lead (E1)' in terms of content, can be powerful and a certain level of flexibility and responsiveness to the group's needs was considered important when delivering goal-setting. However, many

educators recognised that this was a skill that they had developed with experience: “As you get more experienced, you’re thinking, they’re going where they need to go, and it’s a natural conversation that’s happening (E3).”

“Once you have got confidence to let the group lead, you will never go wrong (E7).”

5.5.2.3 Group dynamics.

Educators discussed the impact that group dynamics have on how well goal-setting can be implemented and the differences that exist between groups. Educators described how participants within a group can impact successful delivery and the level to which groups engage with goal-setting.

“If someone is negative towards goals in the group, the group will be negative. If somebody gets annoyed and says why are we spending half an hour on this? This isn't medical, this isn't helpful, you cannot pull them out of that. Whereas if you have a member of the group that is very into that sort of stuff, it will be a totally different session (E7).”

5.5.3 Diversity and individuality.

Diversity and individuality was discussed in relation to both participants and educators. DAFNE participants’ engagement with goal-setting was viewed as diverse and educators were perceived as having different views on the importance of goal-setting.

5.5.3.1 It’s not for everyone.

Most educators felt that the degree to which DAFNE participants benefit from and engage with goal-setting strategies differs per individual with many educators stating “it’s not for everyone (E1)”. Educators mentioned different reasons for this

diversity, including age: “Up to 22-23, is nearly too young emotionally (E9)” or differences in comfort levels: “Not everybody is comfortable with talking about how they feel, or writing it down (E1)”.

> *“Depending perhaps on the type of person one is, you either embrace it, or you say it’s a load of waffle (E4).”*

Some educators highlighted that goal-setting could benefit from more personal guidance to facilitate different coaching levels that participants may require: *“*Some people have lots of detail, and other people will have one word […] people seem to need different levels of coaching (E6)”.

5.5.3.2 Diversity in educators.

While educators did not appear to perceive goal-setting as less important than other DAFNE components, some educators experienced large differences among their colleagues in the importance they placed on this component: “Educator-wise, perhaps 40% embrace and maybe 60% think it’s not as important as the rest of the course (E4)”. Additionally, a difference in attitude between nurses and dieticians was highlighted.

> *“Nurses are trained to help people and to do it for them, to take over […] goals aren't really there if you are doing it for them (E7: diabetes-nurse)”*

Several educators emphasised that the degree to which DSME-educators believe in goal-setting, can impact their delivery style: “I have seen people who are not as confident or not as positive. That they don’t really believe in it, and you do feel a difference (E3)”.

5.5.4 Goal-setting’s fit.

The fourth theme revolves around how educators feel goal-setting and behaviour change practices currently fit within DAFNE and follow-up care.

5.5.4.1 Fit within DAFNE and DSME.

Three educators were generally content with how goal-setting fits within the DAFNE-programme and with the amount of time spent on this component. However, other educators expressed concern about the manner in which goal-setting is addressed within DAFNE and how well it fits with the rest of the curriculum: “It’s an important part, but I am not quite sure that it is working (E1).”

Some educators felt that parts of the goal-setting component are not practical, motivating or user-friendly. The theoretical part was particularly described as clichéd or generic and in need of more practical advice.

> “*look at our curriculum […] it has all these technical terms that really just aren't user friendly for people that just want to chat about something (E1)”.*

Some educators expressed a fear that goal-setting terminology sometimes provokes negative feelings within participants: “If you say we are about to do goal-setting, they often roll their eyes (E7)”. Goal-setting was suggested to be “a very American term, being used for years in funny ways (E7)” potentially evoking reactions of “‘ugh’; here we go (E9)”.

Several educators suggested goal-setting should be addressed continuously throughout the course and feared that currently it is ‘just another session (E1)’, thereby undermining its significance: “It should be brought through every day instead (E7).”

5.5.4.2 Fit within follow-up care.

Many educators argued that following-up with participants to discuss goal-progress after DSME could be important for behaviour change, but highlighted that this does not currently fit with DAFNE, or general diabetes care.

Many educators felt that DAFNE insufficiently incorporates follow-up opportunities to address participants’ goal-progress: “We don’t have enough follow-on

for these patients […] all you can do is provide a taster of behaviour change (E9)". While goal-setting should technically be addressed within a structured DAFNE follow-up meeting, educators admitted that this is rarely put into practice and goals are rarely revisited: "We don't always go back to it […] I focus on all the numbers [...] Do I address their goal? No (E4)".

Several educators highlighted that goal-setting is not considered a priority in clinic appointments and doesn't fit within general diabetes care. Specifically, a lack of time was mentioned as a barrier for engaging in further goal-setting practices with people.

> *"It's generally a time issue. Because you might have a half hour slot […] You kind of have in your head the 'tick-box' about the feet, the eyes, you know, and goals are just not there (E5)".*

Additionally, it was felt that DAFNE-participants rarely revisit their own goals and action-plans, creating additional barriers for goal-progress discussions: "You never see those action-plan sheets again, it is never brought up, it's never talked about (E7)."

5.5.5 Feelings of inadequate psychological knowledge.

5.5.5.1 Less 'black and white'.

Although a few educators were contented with delivering behaviour change content such as goal-setting and action-planning, most educators found this more challenging than other DAFNE-components: "I would feel much less sure (E6)". Several educators perceived goal-setting as less comfortable or enjoyable to deliver, and expressed an awareness of a slightly negative collective attitude towards delivering goal-setting amongst colleagues.

"When we did that session in training, there was definitely a degree of; ah it's great if you don't have to do that session! Because you have to get all touchy feely (E9)"

One challenge discussed, was that goal-setting was less "black and white (E1)" and therefore less predictable: "Other sessions, […] there are hard set rules and kind of this is the way it is, whereas this is just something very different, it is nearly like a psychological session (E10)."

Several educators spoke about goal-setting not lying within DSME educators' "natural skillsets (E6)", as it was considered a reflective moment and some educators felt that issues could emerge that they are not always capable of attending to.

"I am not sure are we best placed to facilitate these sessions […] you feel that there is a lot that patients need at that point, that we are maybe not able to deliver (E9)."

5.5.5.2 Lack of training.

Many educators emphasised that limited training is made available for educators to support the delivery of goal-setting and action-planning elements: "I go to DAFNE collaboratives (*annual HCP-meeting*) and I've never seen a session on goal-setting (E7)".

While the programme-manuals for these sessions were considered valuable, some educators felt that more recommendations would be beneficial to clarify key-content: "I wouldn't be as confident in knowing; what are the elements within goal-setting that actually support the person (E6)". Several educators worried about lacking psychological knowledge, and argued that additional training would be desirable: "It's a bit of a tough session because we're not psychologists (E10)".

"If there would be more training available, I think a lot of educators would appreciate that […] that idea, that one workshop to incorporate goal-setting, I think there is a naivety there, as it's not part of our natural skill-set (E6)."

5.6 Discussion

This study is the first study to explore educators' perspectives on the implementation of goal-setting and action-planning within the DAFNE-programme. Five main themes were identified: people need a plan; the power of the group; diversity and individuality; goal-setting's fit; and feelings of inadequate psychological knowledge.

Overall, educators saw benefits in implementing goal-setting and action-planning strategies within DSME to facilitate behaviour change. Educators highlighted that a group format impacts goal-setting practices and felt that sharing goals and experiences was valuable for participants. This perspective is in line with findings from a recent systematic review, indicating that goal-setting was more effective if goals were set publicly and face-to-face, as opposed to individually or computerised (Epton et al., 2017).

High levels of diversity and individuality were discussed in relation to both participants' and educators' engagement with goal-setting strategies, and goal-setting was viewed as 'not suitable for everyone'. Furthermore, group dynamics were described as powerful, with negative or positive individuals having the ability to influence the group's engagement with goal-setting. While some evidence exists around personality mediating goal-achievement (Klein, Wesson, Hollenbeck, & Alge, 1999), there is limited evidence to support that goal-setting would not be effective for certain individuals. This view could cause educators to accept a lack of engagement more quickly in participants. Therefore, exploring why educators view goal-setting as not

suitable for everyone, and addressing educators' skillset to facilitate group discussion and invert negative group dynamics could be valuable for successful implementation of goal-setting.

DAFNE participants were viewed as requiring different levels of support during goal-setting. While participants were viewed as willing to share their goals, they are not always prompted to do so within group sessions. Goal-setting theory states that goals should meet several theoretical parameters to increase the likelihood of goal-attainment (Latham, 2003). Therefore, individual coaching sessions with a HCP to receive feedback on goal-quality could arguably be beneficial.

Educators raised concerns regarding goal-setting's fits within DAFNE and follow-up care. Many educators felt that parts of DAFNE's goal-setting component are not practical or motivating. Previous research (Lenzen et al., 2016) indicated that HCPs' terminology within goal-setting strategies could lead to feelings of intimidation among people with diabetes. Congruent with these findings, some educators felt that DAFNE's goal-setting terminology was suboptimal, and could elicit negative feelings within participants.

Additionally, many educators highlighted that goals are rarely discussed once DAFNE or DSME is completed and felt that goal-setting is often deprioritised within clinic-visits and DAFNE follow-up meetings. Congruent with previous research in primary care (Blakeman, Macdonald, Bower, Gately, & Chew-Graham, 2006), insufficient time was reported as a barrier for implementing goal-setting strategies within follow-up care. Providing feedback on goal-progress and reviewing and possibly modifying goals have repeatedly been identified as key moderators of goal-setting effectiveness (Latham, 2003). Furthermore, research recommends ongoing support to sustain progress made by participants during DSME-programmes (Norris et al., 2002).

Therefore, giving people a taster of goal-setting within DSME, but failing to address goal-progress afterwards, may not be the best way to facilitate goal-achievement.

While evidence speaks for the positive effects of goal-setting on diabetes self-management (Fredrix, McSharry, et al., 2018), several educators felt that their colleagues varied in the importance they place on this component, and expressed an awareness of a slightly negative collective attitude towards delivering goal-setting amongst colleagues. The interviewed educators expressed several concerns regarding goal-setting's implementation, revealing consistency with this collective attitude. However, most did express a positive attitude towards its importance, disclosing a certain level of inconsistent findings. Therefore it is unclear whether participants were afraid to admit negative attitudes, or if this sample was disproportionately in favour of goal-setting. Nonetheless, addressing educators' concerns by promoting positive attitudes around goal-setting within HCPs may be valuable, as new educators could potentially be primed towards developing negative attitudes. Particularly because, consistent with findings from previous research (Reimers et al., 1987), some educators highlighted that the level to which someone 'believes in goal-setting', could affect delivery style.

Many educators experienced the delivery of goal-setting and action-planning components as more challenging, and described these aspects as less 'black and white', and resembling 'psychological sessions'. Some educators therefore questioned if they were best placed to facilitate these sessions and expressed some feelings of inadequacy regarding psychological knowledge. Arguably, knowledge of behaviour change theory could be beneficial for the delivery of these components (Kok et al., 2016). However, many educators felt that there is a lack of focus on goal-setting and action-planning within training. Knowledgeable and confident educators are crucial for translating

manual-specified content into practice (Anderson & Funnell, 2008). Additional training for educators could help decrease educators' apprehension to engage with goal-setting. Misunderstandings of goal-setting could be addressed by instilling knowledge around its crucial mechanisms and clinical relevance, and skills to guide group discussions in this context could be advanced.

Educators' judgments of a programme's acceptability could influence their interest to implement it with fidelity (Reimers et al., 1987) hereby influencing participants' experiences. Therefore, the perceived challenges around delivering goal-setting components and the concerns regarding goal-setting's fit, could partly explain goal-setting's suboptimal fidelity levels found in previous work (Fredrix, Byrne, et al., 2018). While a certain level of flexibility was regarded as important when delivering goal-setting, most educators spoke in support of adhering to content as outlined in DAFNE-manuals, and felt that their fidelity levels were sufficient. This revealed an inconsistency between self-reported fidelity levels and results from previous work (Fredrix, Byrne, et al., 2018). Future research could attempt to mirror fidelity scores to educators post sessions to explore views on the link between fidelity levels and challenges in delivering goal-setting.

5.6.1 Strengths and limitations.

The present study provides novel, in-depth data on educator's views on the implementation of goal-setting and action-planning components within DAFNE. To ensure rigor in reporting this study's procedures, the COREQ-checklist (Tong et al., 2007) was utilised (Appendix XII). While data saturation was reached, a potential limitation of this work is the convenience sampling strategy and the number of interviewees, which was relatively low (Braun & Clarke, 2013). Furthermore, all participants were Irish, hereby decreasing the findings' generalisability. The one-to-one

interview structure facilitated educators to express individual opinions without the social desirability biases that could surface in group-based data collection methods. A possible limitation lies within the analyses, as coding was primarily conducted by one researcher. However, coding was discussed with a second researcher at each stage of the analysis, and identified themes were checked against original transcripts. The themes are closely related to the raw data to reduce contamination factors (Braun & Clarke, 2013), and are therefore mostly descriptive.

5.7 Conclusion

DSME educators are encouraged to embrace behaviour change strategies as goal-setting and action-planning to promote person-centred education. However, this study shows that while educators see value in implementing these strategies, many questioned how well goal-setting currently fits within DAFNE. Educators highlighted that the level of follow-up with people to discuss goal-progress after DSME-programmes could be significantly improved. Furthermore, many educators experienced the delivery of these behaviour change components as challenging and felt that training insufficiently addressed the operationalisation of goal-setting strategies. To improve educators' experiences, reconsidering educators' training could be valuable. Additionally, some educators questioned whether HCPs are best placed to deliver goal-setting. Therefore, involving psychologists or behaviour change expert might benefit the implementation of DSME-programmes such as DAFNE.

Future research should explore whether these views are consistent across DSME-programmes and countries. Additional research could explore how educators' behaviours are influenced by their concerns surrounding DAFNE's implementation of goal-setting. Furthermore, projects addressing the optimisation of DAFNE, such as DAFNE-plus (Brennan, Pollard, Coates, Strong, & Heller, 2017), could integrate these

findings in the modification of goal-setting content, or optimisation of educators' training.

6. General discussion

6.1 Discussion overview

This chapter will present a summary of the overall findings of this research and discuss the contribution made by this research to creating a better understanding of goal-setting behaviours in a diabetes context. The research findings will be discussed in relation to existing literature and the implications of the findings for practice and future research will be highlighted. Limitations of the PhD project and approaches to addressing these limitations will be discussed. The final section of this chapter will contain overall concluding remarks.

6.2 Summary of research findings

The overall aim of this research was to explore the effectiveness and implementation of goal-setting techniques in diabetes self-management interventions and to explore the implementation of goal-setting techniques in DAFNE, a prominent Diabetes Self-Management Education (DSME) programme for people with T1DM. Overall, this research has advanced our understanding of the effectiveness and implementation of goal-setting techniques in a diabetes context in a number of ways.

The systematic review described in study 1 created an evidence base around the content and effectiveness of goal-setting interventions targeting diabetes outcomes. The review found tentative evidence to suggest that patient centred goal-setting interventions, targeting diabetes outcomes in people with T1DM and T2DM can have a positive effect on average blood glucose levels. Across the included interventions, ‘Goal-setting (behaviour)’ emerged as the most frequently implemented BCT while

BCTs from the ‘Feedback and monitoring’ cluster were rarely included. Despite efforts to identify relationships between the presence of specific BCTs and intervention outcomes, the low numbers of included studies limited the feasibility of these analyses. Therefore, the relatively small numbers of existing studies and the risk of potential bias across studies do suggest that more research is needed to create more robust findings.

Building on the evidence base created in study 1, a content and fidelity study explored how goal-setting is currently addressed and delivered in a prominent T1DM DSME-programme, by systematically assessing the content and implementation fidelity of the goal-setting component of the DAFNE programme. Study 2 identified 13 different BCTs (Michie et al., 2013) within the intervention manuals of DAFNE’s goal-setting sessions that were operationalised a total of 41 times throughout the sessions. The majority of included BCTs originated from the ‘Goals and planning’ BCT cluster of the BCTTv1. In line with findings from study 1, there was limited inclusion of feedback and monitoring BCTs.

Observational data revealed that on average, DAFNE educators only tended to deliver around half of the manual-specified BCTs in practice when delivering DAFNE’s goal-setting component. This indicates that overall fidelity scores were close to being classified as low (Borrelli, 2011; Lorencatto et al., 2013). Additionally, high levels of variation were found in fidelity scores between sessions, educators and BCTs. Session duration was not correlated with fidelity of delivery across observed DAFNE goal-setting sessions. Therefore, it could be argued that time-pressure was not a contributing factor to low levels of fidelity throughout the study.

Qualitative interviews with HCPs, who were trained DAFNE educators, revealed that educators saw the benefits of implementing goal-setting and action-

planning strategies in DAFNE and DSME programmes. However many educators expressed concerns about how well goal-setting currently fits within DSME and follow-up care. Congruent with findings from study 1 and 2, educators highlighted that limited feedback is made available for DAFNE participants after DSME programmes are completed, and that goal-setting practices are commonly deprioritised in follow-up visits and routine diabetes clinic appointments.

While a certain level of flexibility was regarded as important when delivering goal-setting, most educators spoke in support of adhering to content as outlined in DAFNE-manuals, and felt that their fidelity levels were sufficient. This revealed an inconsistency between self-reported fidelity levels and the results from study 2. However, the relatively low fidelity scores found in study 2 could in part be explained by the fact that many DAFNE educators experienced the delivery of goal-setting and action-planning strategies as more challenging and felt that training insufficiently addressed the operationalisation of these strategies. Additionally, some educators questioned whether HCPs are best placed to deliver goal-setting components in DSME as many educators expressed feelings of insufficient psychological knowledge.

6.3 Contribution of this research

Diabetes stakeholders selected ‘collaborative goal-setting with patients’ as a HCP priority behaviour for diabetes research in Ireland, and considered this to be a valuable behaviour to target in future intervention development (Mc Sharry et al., 2016). The findings of this research have contributed significantly to a clearer understanding of HCPs’ goal-setting behaviour in a diabetes context.

In the Chronic Care Model, Bodenheimer, Wagner, et al. (2002) highlighted that chronically ill people need higher levels of person-centred care strategies such as collaborative goal-setting. Goal-setting and action-planning strategies have since been increasingly included in guidelines for diabetes support (Beck et al., 2017; Chin et al., 2007; Haas et al., 2012). However, clarity was lacking regarding the effectives of goal-setting strategies in a diabetes context. Previous individual studies had indicated that collaborative goal-setting in diabetes support was associated with increasing patients' self-efficacy level, higher self-management motivation and higher levels of intrinsic motivation leading to better self-management skills (Estabrooks et al., 2005; Marks & Allegrante, 2005; Williams et al., 2007). However, the effectiveness and implementation of goal-setting in a diabetes context had not been previously investigated in a systematic way. Addressing this gap in the literature, study 1 provides a systematic evidence base regarding the effects of goal-setting strategies on health and behavioural outcomes in people with diabetes.

The findings from the systematic review in study 1 tentatively suggest that, when goal-setting is implemented as a primary intervention strategy targeting diabetes outcomes, there is an overall positive effect of goal-setting interventions on average blood glucose levels. Furthermore, a clear overview is provided of existing goal-setting interventions' active content, and effects on a wide range of clinical, health, psychosocial or behavioural outcomes in people with diabetes. These findings can function as an evidence base to guide future goal-setting intervention development, and help shape evidence based practice. However, the small number of available studies also stresses the importance of further research in this area.

Additionally, a clearer understanding has been created of how goal-setting strategies are currently implemented in a T1DM health-care setting and which barriers and facilitators to successful implementation of these strategies exist. A clear overview is given around the mechanisms by which behaviour is suggested to change by the goal-setting component of DAFNE, which can inform future programme optimisation or development (Craig & Petticrew, 2013; Michie et al., 2013). Additionally, the relatively low fidelity of delivery scores for DAFNE's goal-setting component, and the large disparities in fidelity scores, imply that even in an area of diabetes support, where goal-setting strategies are structurally and consistently implemented, implementation issues can arise.

When pursuing changes in health-care or HCPs' behaviours, implementation science suggests that prior to intervention or policy development, potential issues surrounding the implementation of these proposed changes must be carefully considered (Elmore, 1979). Therefore, HCPs' perspectives on the implementation of goal-setting strategies within DSME were explored to assess possible barriers and facilitators to applying these strategies in practice. The qualitative data in study 3 highlights that issues such as a lack of training, and feelings of inadequate psychological knowledge, should be addressed when implementing or optimising goal-setting strategies in future DSME and diabetes support.

6.4 Goal-setting theory and goal-setting in practice

The concept of goal-setting plays a prominent role in several psychological and behaviour change theories (Austin & Vancouver, 1996). Previous research has suggested that goal-setting strategies have the ability to facilitate behaviour change

through motivating our actions and regulating our behaviour (Latham, 2003; Latham & Locke, 1991). However, theories such as ‘Goal-setting theory’ (Locke & Latham, 2002), ‘Self-Determination Theory’ (Ryan & Deci, 2000), ‘Social Cognitive Theory’ (Bandura, 1986) and the ‘Health Action Process Approach’ (Schwarzer & Luszczynska, 2008) suggest several theoretical determinants to be associated with more successful goal-striving and achievement. These determinants range from psychosocial factors such as self-efficacy levels, to goal attributes and implementation of supporting strategies such as action-planning (Locke & Latham, 2002). For example, setting specific, challenging yet achievable goals in terms of behaviour tends to lead to better performance, as compared to unchallenging goals, or vaguely defined outcome goals (Locke & Latham, 2002; Strecher et al., 1995). Additionally, incorporating feedback and action-planning strategies in goal-setting practices is believed to enhance goal achievement (Locke & Latham, 2002). Through exploring the implementation of goal-setting techniques in diabetes self-management interventions and within a T1DM DSME programme, this research created a better understanding of the current application of these theoretical constructs in practice.

Just over half of the included interventions in the systematic review reported the use of theory, with Social Cognitive Theory (Bandura, 1986) and Self-Determination Theory (Ryan & Deci, 2000) most frequently applied. However, many studies failed to report how these theories had guided the process of intervention development. Additionally, goal-setting theory highlights several goal-attributes that can impact goal-striving and achievement (Locke & Latham, 2002). While all included interventions highlighted that goals were patient-driven, which is in line with self-determination theory (Ryan & Deci, 2000), very little information was given regarding the types of

goals that were set and their individual difficulty levels or characteristics. Kok et al. (2016) argue that when implementing a behavioural change method such as goal-setting, certain conditions must be satisfied in practical application for a method to be effective. For example, goal-setting can be an effective method for behaviour change, but only if a goal is relevant and challenging while still achievable (Kok et al., 2016). If people choose goals that are outside of these 'theoretical parameters', this could impact on intervention effectiveness. Therefore in future intervention research, more reporting on goal quality and goal-characteristics and practical application of behaviour change methods should be included when describing intervention effectiveness, as these could affect intervention outcomes.

Congruent with the interventions included in the systematic review, the mechanisms by which behaviour was suggested to change in the goal-setting component of DAFNE, as identified through the BCT coding of the DAFNE manuals, included limited opportunity for goal-quality assurance. While participants receive information on what a high quality goal should look like, by using the theoretically grounded SMART acronym (Abraham & Michie, 2008), the active content of these sessions did not include participants receiving feedback on their set goals. Making sure that people set goals that meet theoretical parameters can be an important step towards goal-achievement (Kok et al., 2016). Additionally, the fidelity work revealed that 'goal-setting behaviour' was the least consistently delivered BCT across observations. Setting goals in terms of behaviour is theorised to be more effective then setting goals in terms of outcomes, as behaviours are more directly under people's control and are more strongly related to concentration, effort and persistence (Strecher et al., 1995).

‘Feedback and monitoring’ BCTs were rarely included in interventions in the systematic review. Moreover, the content analyses of DAFNE’s goal-setting component identified no feedback or monitoring BCTs. The qualitative interviews with DAFNE educators revealed that a lack of follow-up strategies for goal-setting practices was seen as a cause for concern. The overall lack of feedback BCTs in the current application of goal-setting was incongruent with theory, as ‘goal-setting theory’ suggest consistent feedback loops can have a significant impact on goal-setting as an active ingredient in health interventions (Latham, 2003). Furthermore, a systematic review of implementation interventions for diabetes care (Presseau, 2016), suggested that ‘feedback on outcomes of behaviour’ seemed to be the most powerful BCT in reducing HbA1C in people with diabetes. Implementing more ‘feedback and monitoring’ techniques when implementing goal-setting strategies in diabetes support, could potentially improve goal-achievement and increase intervention effect sizes (Locke & Latham, 2002; Strecher et al.,1995).

Findings from this research indicate that implementing goal-setting techniques within future diabetes self-management interventions and support appears to be advisable. However, it is important to highlight that goal-setting is a complex process and if implemented, should be implemented properly using a theoretical base (Locke & Latham, 2002). The current application of goal-setting in practice, as highlighted in this research, reveals several disparities from theoretical constructs. This suggests that there is room for improvement in terms of theory application in diabetes support. Using theories such as ‘goal-setting theory’ to inform appropriate application of BCTs and guide intervention development is recommended, as it is suggested to increase the

likelihood of successful behaviour change, and could increase the effects of goal-setting strategies (Michie et al.,2011; Kok et al., 2016).

6.5 Implications for practice

6.5.1 Informing future healthcare.

While goal-setting and action-planning strategies are increasingly included in guidelines and recommendations for diabetes support and have become essential parts of many primary care improvement schemes (Beck et al., 2017; Chin et al., 2007; Haas et al., 2012), clarity surrounding the effectiveness of goal-setting in this context was lacking. While the results of this research may need to be approached with caution, the findings from the systematic review suggest that person-centred goal-setting strategies have a positive outcome on diabetes health outcomes. Therefore, integrating goal-setting within diabetes support strategies seems beneficial and should be further explored.

Previous work by Darker et al. (2015) data revealed that in Ireland, only a minority of people with diabetes reported being asked about their ideas or goals when making a treatment plan with HCPs. Findings from the qualitative data from study 3 support this data as HCPs admit to deprioritising goal-setting in routine diabetes care. To address chronic health care issues such as this, the Irish Health Service Executive (HSE) recently released a new framework for chronic care in Ireland (Healthy Ireland, 2017). In this framework, recommendations are made for the implementation of improved self-management support in Ireland, along with a plan for initial implementation. The HSE aims to increase and optimise self-management support that is underpinned by a communicative relationship between the patient and the HCP and

includes collaborative goal-setting as a key component. As person-centred goal-setting is essential to this care improvement scheme, the findings from this research validate the positive effect that this framework could have on diabetes self-management outcomes. To put schemes like these in place, actions are required at the levels of the patient, the HCP, and the health care system (Healthy Ireland, 2017). However, several barriers and facilitators to successful implementation of goal-setting strategies in diabetes support systems are highlighted in this research.

The findings from study 2 highlight the need to address implementation fidelity before, during and after interventions or changes to healthcare systems are implemented. These findings show that even when goal-setting and action-planning strategies are structurally and consistently implemented, and allocated to a specific time-slot within diabetes support systems, implementation issues can still arise. These levels of fidelity are not unusual and are consistent with implementation fidelity outcomes within other behaviour change interventions (Borrelli et al., 2005; Griffin et al., 2009; Hardeman et al., 2008; Lorencatto et al., 2013; Schinckus et al., 2014; Whittemore et al., 2010). However, while quality of delivery can be suboptimal and fidelity of delivery tends to reduce over time, research has shown that HCPs are capable of delivering behaviour change interventions within the time constraints of primary diabetes care (Avery et al., 2016). Nevertheless, monitoring implementation fidelity and providing feedback and sufficient training to HCPs is crucial (Bellg et al., 2004). A recent Cochrane review by Ivers et al. (2012) found that providing HCPs with feedback on their performance generally leads to improvements in professional practice, particularly if feedback is given more than once.

Additionally, Bellg et al. (2004) suggest adequate training as a crucial part of ensuring implementation fidelity of healthcare programmes or interventions. The qualitative data from study 3 suggested that DAFNE educators frequently reported feelings of having insufficient knowledge surrounding the operationalisation of goal-setting and action-planning content. Furthermore, a desire for more training in this area was commonly reported. Training for HCPs is crucial to prevent skill deterioration and increase fidelity of delivery of interventions or healthcare practices (Bellg et al., 2004). If future diabetes support improvement schemes are aiming to promote collaborative goal-setting in diabetes, more training for HCPs in psychological and behaviour change topics therefore seems essential (Hunter, 2016; Perrin et al., 2006). Knowledge and skill building could take place at an educational level throughout undergraduate and graduate degrees or at a professional level by developing and implementing interventions and training models targeted at qualified HCPs working in chronic care (Healthy Ireland, 2017).

In addition to training and implementation fidelity, future care optimisation will need to address attitudes towards goal-setting strategies in diabetes support. Several DAFNE educators expressed an awareness of a collective negative attitude surrounding the implementation of goal-setting strategies. Furthermore, all educators felt that goal-setting was deprioritised in routine diabetes care. A study by Glasgow et al. (2002), strove to implement patient centred self-management support, underpinned by collaborative goal-setting, by introducing a training programme for HCPs. Data revealed that the most successful implementation of these strategies occurred in HCP teams where attitudes and views had changed. When HCPs recognised the centrality of person-centred, collaborative goal-setting and self-management support as the bases of

good care, rather than seeing it as optional additional component, significantly higher levels of implementation occurred. Furthermore, Reimers et al. (1987) suggest that HCPs' judgments of an intervention or programme's acceptability can influence their interest and willingness to deliver and implement it with fidelity. Therefore, in optimising diabetes support, targeting HCPs' attitudes towards the implementation of goal-setting strategies, could be vital in increasing goal-setting behaviours (Perrin et al., 2006). To increase the likelihood of successful implementation of future diabetes care improvement schemes promoting goal-setting, such as the 'HSE chronic care framework' (Healthy Ireland, 2017), these barriers and facilitators should be considered and addressed.

6.5.2 Informing existing healthcare structures.

The MRC framework for developing and evaluating complex interventions suggests that optimising and exploring the mechanisms of interventions that have already been implemented, and integrating new knowledge within an existing framework increases the impact of research and enhanced the feasibility of change to the healthcare system (Craig et al., 2008, 2013; Craig & Petticrew, 2013). The findings from this research could feed into the optimisation of existing DSME programmes such as DAFNE, hereby increasing their chances of success. A recent questionnaire based study looking at the goal-setting component of a T2DM DSME programme, found tentative results that goal-setting as part of a DSME programme can have positive effects on participants' ability to set and attain behaviour change goals (Donnell et al., 2018). However, in line with the findings from this research, Donnell et al. (2018) suggest that the implementation of goal-setting within DSME could be improved. It

appeared that only 1 in 5 participants claimed to have discussed their goal with a HCP after the DSME programme was completed. This issue of follow-up opportunities was well represented within the qualitative data of study 3.

Issues such as the lack of focus on people's set goals in follow-up meetings after DSME programmes end, and the perceived lack of practicality of goal-setting content, could be addressed within existing DSME programmes. Adding structural follow-up opportunities and providing additional training on a continuous basis for educators, could help decrease educators' apprehension to engage with goal-setting within DSME and follow up care. Furthermore, training or additional guidance in intervention manuals could address misunderstandings of goal-setting by instilling knowledge around its crucial mechanisms and clinical relevance.

6.5.3 The role of behaviour change and psychology in diabetes support.

On a wider level, it could be beneficial to create more opportunities for psychologists or behaviour change experts to support HCPs in the implementation of behaviour change constructs such as goal-setting. Skills and competence have been recognised as significant obstacles to transferring evidence-based findings into clinical practice (Dewing et al., 2013). Due to the perceived challenges for HCPs in delivering person-centred care and behaviour change strategies, arguments are frequently made that psychologists should be integrated more within primary diabetes care (Hunter, 2016). Furthermore, some research claims that researchers focusing on behavioural or psychosocial aspects of diabetes should be trained to work within interdisciplinary teams to ensure evidence translation in real life settings (Czajkowski et al., 2015; De Groot & Fisher, 2011; Hunter, 2016). However, while organisations as the American

Diabetes Association (2015) recommend that good quality diabetes care should include psychosocial screening and interventions or referrals to mental health specialists if necessary, psychologists are rarely involved in routine diabetes care and support (De Wit, Pulgaron, Pattino-Fernandez, & Delamater, 2014; Ducat, Philipson, & Anderson, 2014).

In addition to this, there is limited room within DSME programmes for psychologists or behaviour change experts (Hunter, 2016). DSME programmes are structurally implementing more behaviour change strategies such as behavioural goal-setting, action-planning and problem-solving and are introducing psychological constructs from models of behaviour change (Grant et al., 2013; Prochaska & Velicer, 1997). However, findings from study 2 and 3 suggest that it can be challenging for HCPs to take complex behaviour change constructs, and deliver them with confidence and fidelity. Furthermore, some educators question whether HCPs are best placed to deliver components such as goal-setting. Therefore, arguments could be made for the involvement of psychologists or behaviour change experts in future DSME programmes and diabetes support. Creating opportunities for psychologists to support HCPs or be more directly involved in intervention delivery could improve the implementation of behaviour change strategies such as goal-setting in a diabetes context.

6.6 Implications for research

This research has contributed to our understanding of the effectiveness and implementation of goal-setting behaviours in a diabetes context. The positive effects of goal-setting behaviour change interventions have been suggested in previous research (Epton et al., 2017), but lacked clarity in the area of diabetes. Study 1 has provided a

strong evidence base surrounding the effectiveness of goal-setting interventions in the area of diabetes, by identifying existing interventions and establishing the mechanisms of change and methods that were used to evaluate these interventions. The outcomes from the systematic review suggest the implementation of goals and planning BCTs is advisable in the development of future interventions targeting diabetes self-management behaviours. Furthermore, this systematic review offers an example of a methodologically rigorous strategy to evidence synthesis of intervention studies. While some limitations were apparent, utilising the BCTTv1 was shown to be a reliable measure of synthesising and summarising intervention content within a systemic review, and a similar approach would be recommended for future research.

Additionally, this research provides an example of a systematic and valid method for assessing the active content and fidelity of a structured education programme. Healthcare systems invest substantial means into quality improvement efforts that aim to optimise diabetes care and develop DSME programmes, and to maximise outcomes effects and minimise the implementation of unsuccessful interventions (Grimshaw et al., 2006). Specifying the components of an intervention and verifying that they are delivered and delivered well is vital for sound research practice (Santacroce et al., 2004). Therefore, making sure that reliable methods exist to monitor the quality with which interventions are implemented and delivered is crucial (Muse & McManus, 2013). Applying the BCTTv1 to reliably code the active content of the goal-setting component of DAFNE was a novel but necessary approach, as it provides clarity around the mechanisms by which behaviour is suggested to change within a structured education programmes (Craig & Petticrew, 2013; Michie et al., 2013).

Furthermore, by utilising the BCTTv1 (Michie et al., 2013) as a tool to quantify fidelity of delivery, this study provides an example of a systematic and valid method to assess implementation fidelity within a structured education programme, that can be applied in future implementation fidelity research. Contrasting the findings from study 2, the qualitative data in study 3 revealed that most educators spoke in support of adhering to content as outlined in DAFNE-manuals, and felt that their fidelity levels were sufficient. This revealed an inconsistency between self-reported fidelity levels and observed fidelity scores in study 2. These findings highlight the importance of utilising objective measures to assess implementation fidelity in future research, as self-reported data could be subject to bias.

The importance of examining implementation fidelity is widely recognised, however research shows that it is often not assessed within intervention research (Bellg et al., 2004; Schinckus et al., 2014). Furthermore, fidelity research mainly focuses on evaluating new interventions (Schinckus et al., 2014). This research emphasises the significance of continuous monitoring of implementation fidelity after interventions or health programmes are implemented in practice.

As the importance of implementation fidelity is increasingly emphasised in intervention and healthcare research (Boutron et al., 2008; Craig & Petticrew, 2013), an intensifying debate surrounds the balance between fidelity of programme delivery and adaptation of the programme to the local context. Arguments have been made that the modification of programme content by HCPs, to address the needs of a specific participant group, is essential (Borrelli, 2011; Hawe et al., 2004; Kemp, 2016). Within previous work by Hawe et al. (2004), arguments are made for fidelity to be defined as the degree to which the delivery of components fits with the theory or principles of the

hypothesised change process. These views could be beneficial in making programmes more adaptable and give HCPs more freedom to use their expertise in the implementation of interventions and healthcare-programmes (Hawe et al., 2004). However, there is a level of knowledge required regarding the theory in question on the part of the HCP. Study 3 revealed that several educators expressed a certain level of insecurity regarding their knowledge on identifying the key elements within components such as goal-setting and action planning. This was highlighted in the results of study 2 with 'goal-setting behaviour' being the least consistently delivered BCT across observations, even though setting goals in terms of behaviour is theorised to be more effective then setting goals in terms of outcomes (Strecher et al., 1995). While HCPs have expertise that should be used to full advantage, they might not have the expertise in behaviour change topics such as goal-setting and action-planning. This research thus suggests that identifying priority BCT content and incorporating clearer guidelines on adaptation or personalisation within future intervention and programme manuals is crucial. This could offer meaningful benefits to consistent programme delivery and would add to the scientific rigour of the educational intervention's approach and in turn could improve intervention outcomes (Hasson et al., 2012; Keith et al., 2010; Schinckus et al., 2014) .

Previous research has suggested that facilitators' judgments of an intervention's or programme's acceptability could influence their interest to implement it with fidelity, hereby influencing participants' experiences (Reimers et al., 1987). DAFNE educators perceived challenges around delivering goal-setting components and the concerns regarding goal-setting's fit found in study 3 could partly explain goal-setting's suboptimal fidelity levels found in study 2. Therefore, in optimising implementation

fidelity and intervention acceptability, this research highlights the importance of exploring the views of stakeholders who are responsible for the delivery and implementation of programmes or interventions.

Finally, this research contributes to a foundation for the development of a complex intervention targeted at increasing goal-setting behaviours in HCPs (Craig & Petticrew, 2013). While more research is needed to assess additional barriers of implementing goal-setting as part of routine care on a larger national scale, this research has identified several barriers and facilitators to successful implementation of goal-setting in diabetes support. These barriers should be addressed in future research or the systematic development of interventions targeting goal-setting behaviour in HCPs (Bartholomew, Parcel, Kok, Gottlieb, & Fernandez, 2011).

6.7 Strengths and limitations

6.7.1 Strengths and limitations of the individual studies.

The systematic review exploring the content and effectiveness of goal-setting interventions targeting clinical, health, psychosocial or behavioural outcomes in people with diabetes described in study 1 was carefully conducted with respect for scientific rigour. The review was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher et al., 2009) (for completed PRISMA checklist see Appendix II) and was based on a detailed pre-registered online protocol. Furthermore, all extracted data and risk of bias assessments were independently checked by a second author and all BCT coding was conducted independently by two authors. The search strategy was detailed and comprehensive, included several databases and was published online to promote

research transparency (Appendix III). The review included studies with different research designs, which could be seen as a limitation as it increases heterogeneity among studies. However, by including a wider variety of study designs, a more complete overview has been created of existing goal-setting interventions targeting diabetes outcomes, hereby strengthening the evidence base.

The greatest challenge of the systematic review was extracting sufficient data to pool effect sizes. Therefore, due to the relatively small number of studies included in the meta-analyses, caution must be applied when generalising the findings. Additionally, the clinical significance of findings should be considered. HbA1c reductions of 0.3% are suggested to be clinically relevant (Avery et al., 2012). Therefore, while statistically significant, the average reduction of 0.22% in HbA1C found in the meta-analysis is thus marginally short of clinical significance.

Despite our best efforts to include studies targeted at people with T2DM and T1DM, only one of the interventions included people with T1DM in their sample, indicating a lack of goal-setting interventions targeting T1DM. Many similarities exist between self-management behaviours for T1DM and T2DM, and drawing information from research conducted in the areas of both T1DM and T2DM was valuable to create an evidence base for the overall effectiveness of goal-setting strategies in a diabetes context. However, there are also substantial differences in the management of both illnesses (Ahlqvist et al., 2018). T2DM, particularly in its early stages can be managed largely by setting life-style goals, while T1DM often requires setting goals focused on medication adherence (Ahlqvist et al., 2018). These differences in illness management could lead to the development of different types of goals in behaviour change interventions. Mostly including one type of diabetes therefore could have an impact on

the generalisability of the findings of the review. Therefore, future interventions utilising goal-setting strategies as a core component, should aim to target people with T1DM. This will create a better understanding of the effectiveness of goal-setting strategies across different types of diabetes.

The review set out to not only assess overall effectiveness, but to identify relationships between specific BCTs and intervention outcomes. The paucity of intervention studies meant that this analysis was limited. Furthermore, no grey literature was included within this review to ensure a higher quality of included studies. However, as indicated by a significant risk of publication bias, it is possible that more studies have been conducted without being published (Hopewell et al., 2009). Future research could aim to include grey literature to strengthen the evidence synthesis.

Systematic review results are only as reliable as the studies included in the review (Garg et al., 2008) and there were some weaknesses in the studies included in this review as can be seen in the risk of bias summary. While quality assessment did not result in studies being excluded, details related to the risk of bias were provided to allow readers to determine the weight that should be assigned to each study included in the review.

Additionally, studies that reported a control condition provided limited information on what this entailed, and often referred to this as ‘usual care’. Therefore, some forms of goal-setting could have taken place within usual care and could therefore affect the reliability of the data. Furthermore, while goal-setting was the primary intervention strategy for the included studies, most interventions did not rely exclusively

on goal-setting techniques. Additional BCTs appeared in several studies. Therefore, the full range of effects could have been spread over these additional BCTs.

Study 2 utilised systematic approaches towards describing the active content of the goal-setting component of DAFNE. Describing intervention content in terms of BCTs using the BCTTv1 has been demonstrated as a feasible classification method and is becoming increasingly standardised within behaviour change research (Lorencatto et al., 2013; Michie, Abraham, et al., 2009; Michie et al., 2013). Furthermore, all BCT coding of the programme manual was conducted independently by two authors with good inter-rater agreement reported. Additionally, the BCTTv1 was utilised to assess implementation fidelity of the goal-setting component of DAFNE by comparing the active content of the programme-manuals with the transcripts of corresponding DAFNE observations. While relatively novel, this method has been utilised in previous research as a systematic and reliable way of assessing implementation fidelity (Lorencatto et al., 2014; Lorencatto et al., 2013). Highlighting the reliability of this method, 20% of all observations were double coded for fidelity by a second independent researcher, with a good inter-rater agreement.

While study 2 aimed to ensure methodological rigour through using systematic ways of assessing implementation fidelity, the area of implementation fidelity is relatively novel. Therefore, there are limited guidelines in place surrounding sample-size and power of implementation fidelity research (Bellg et al., 2004). Study 2 was limited by the availability of DAFNE-courses in Ireland, leading to a relatively small samples size. Therefore, while the wide range of fidelity scores remains valid, the generalisability of the averaged fidelity scores could be limited. Future research should aim to include a higher number of observations, to create more robust findings.

Additionally, demand characteristics could have influenced fidelity levels, as educators may have attempted to improve their delivery. While these sessions may therefore not be representative of typical practice, the sessions are more likely to over-estimate rather than under-estimate fidelity scores.

The analyses of study 2 focussed mostly on the design and delivery dimensions of implementation fidelity, as it assesses the content of the manuals and how well educators adhere to these manuals. While most implementation fidelity research is conducted in this manner, future research should attempt to assess fidelity across all dimensions. Assessing whether educators are properly trained to delivered the programme (training), the degree to which participants initially understand and engage with the programme (receipt) and apply content as intended in a real-life setting (enactment) should be addressed in future research to create a more complete overview of fidelity (Bellg et al., 2004; Borrelli, 2011). Furthermore, associations between fidelity and programme effectiveness were not assessed within this study. While previous research suggests that differences in fidelity could represent a potential factor in explaining variation in participants' outcomes (Bellg et al., 2004; Ellis et al., 2007), future research will have to explore this relationship further by examining the association between goal-achievement and fidelity scores.

In the third study, efforts were made to avoid bias throughout data collection and analyses. To ensure rigour in reporting this study's procedures, the COREQ-checklist (Tong et al., 2007) was utilised (Appendix XII). Additionally, a topic guide was created and followed throughout data collection (Appendix XIII). To make participants as comfortable as possible, the topic guide included 'warm up' questions that were designed to make participants familiar with the interview setting. Furthermore, when

possible the interviews took place in settings that were familiar to the participants (primary care setting, diabetes clinic). The one-to-one interview structure facilitated educators to express individual opinions without the social desirability biases that could surface in group-based data collection methods.

Data saturation was reached in study 3, however a potential limitation of this study was the convenience sampling strategy and the number of interviewees, which was relatively low (Braun & Clarke, 2013). Furthermore, while participants were deliberately recruited from four different diabetes clinics to promote diversity, all participants were Irish and female, which could limit the findings' generalisability. Future research should aim to collect more data from a higher number of participants, and explore whether these views are consistent across DSME-programmes, gender and countries.

The author of this thesis was both responsible for conducting the interviews and for the data analysis in study 3. Therefore, factors such as the researchers' beliefs, educational background, experiences and personality could have led to a subjective interpretation of the data (Braun & Clarke, 2013). Including a second independent researcher to double code all data could have reduced the risk of subjective interpretation (Ziebland & McPherson, 2006). However, following guidelines by Braun and Clarke (2013), qualitative work requires a certain level of personal reflexivity and the researchers background was acknowledged within the COREQ-checklist. Furthermore, coding was discussed with a second researcher at each stage of the analysis, and identified themes were checked against original transcripts. Additionally, the identified themes are closely related to the raw data to reduce contamination factors

(Braun & Clarke, 2013). However, the themes are therefore mostly descriptive, and could arguably benefit from an additional layer of analyses (Braun & Clarke, 2013).

6.7.2 Strengths and limitations of BCT coding.

Throughout this PhD project, the BCTTv1 has been applied in multiple ways. Through these different applications, several strengths and limitations have become apparent. As the utilisation of BCT taxonomies is increasing in health research (Michie et al., 2018), these strengths and limitations could provide valuable insights for future research.

Studies 1 and 2 of this research both utilised the BCTTv1 to identify the active components of goal-setting interventions. While other strategies exist for describing intervention content within the field of behaviour change (Kok et al., 2016), the BCTTv1 was utilised in this research as it describes the different types of goal-setting most clearly (McEwan et al., 2016; Michie et al., 2013). The BCTTv1 was introduced to provide a shared language, and a precise and systematic method for describing the active content of interventions (Michie et al., 2013). Consequently, the BCTTv1has been increasingly used to retrospectively code intervention components in systematic reviews (Avery et al., 2015; Dombrowski et al., 2012; Morrissey et al., 2017; Presseau et al., 2015). However, a recent scoping review by (Michie et al., 2018) revealed that studies using the taxonomy in this manner often report a lack of confidence in their findings due to methodological limitations. These limitations include issues such as: research heterogeneity; a lack of published studies; a lack of clear intervention descriptions; and limited fidelity of delivery assessment in published studies. Congruent

with findings from this review, studies in this research using the BCTTv1 faced several challenges.

Within the systematic review, BCTs were coded for presence and frequency of techniques but not for the quality with which they were delivered or implemented. The BCTTv1 is often criticised for only capturing a segment of what theory states about active content of interventions (De Bruin, Crutzen, & Peters, 2015). For example, in an alternative taxonomy of behaviour change methods, Kok et al. (2016) argue that certain conditions, or 'theoretical parameters' must be satisfied in the practical application for a behaviour change method to be effective. The BCTTv1 disregards whether theoretical parameters are met within an intervention to ensure optimal use of a BCT (de Bruin, Viechtbauer, Hospers, Schaalma, & Kok, 2009). However, retrospectively coding of such information would require extremely detailed and systematic intervention descriptions, which is often lacking in published research.

This lack of detail in intervention description creates a second limitation when applying the BCTTv1 to retrospectively coding of intervention content. Within the systematic review, the coding was limited by the amount of information provided in papers or given by authors. As has been frequently observed in the behaviour change literature (Riley et al., 2008), studies did not always report the content of the interventions in sufficient detail. This could have resulted in some coding difficulties and it is possible that, in some cases, the content of studies has not been accurately captured. Additionally, studies rarely report information regarding the extent to which BCTs are delivered as planned (Michie et al., 2018). The data from study 2 revealed that fidelity of delivery of BCTs can be suboptimal in practice. Fidelity issues, combined with poor reporting of interventions procedures, can lead to significant differences

between the BCTs coded within an intervention report and the BCTs that were actually delivered in practice. This could have negative consequences for the reliability of evidence syntheses (De Bruin et al., 2015; Johnson & Michie, 2015; Michie, Johnson, & Johnston, 2015), and should be considered in interpreting the findings and applying them to future research or practice (de Bruin et al., 2009).

As the complete DAFNE intervention manual was made available in study 2, coding the active content of DAFNE's goal-setting components in terms of BCTs was proposed to be more thorough than the retrospective coding of interventions in the systematic review. Most behaviours described within the DAFNE manual were accurately and reliably captured within the BCT analysis. However, a few behaviours listed within the manual, that were recommended for educators, did not fit within any of the BCT categories outlined in the BCTTv1. Michie et al. (2013) recognise this limitation and acknowledge that more development work is needed to create a more complete taxonomy for future use.

In line with the systematic review, the findings from the fidelity assessment in study 2 were somewhat limited by not fully assessing the quality or intensity with which BCTs were delivered. Attempts were made to address quality of BCTs delivery by coding BCTs as delivered wholly or in part (Michie et al., 2018). However if a BCT is delivered, but delivered poorly or without enthusiasm, this could affect the degree to which full implementation occurs (Lorencatto et al., 2013). While this limitation has been flagged in previous implementation fidelity research (Lorencatto et al., 2014; Lorencatto et al., 2013; Sweeney-Magee et al., 2016), no clear guidelines have been developed around assessing quality of BCT delivery to date. Future research should aim

to provide more clarity or guidelines to assess quality of BCT delivery in intervention research.

Using taxonomies to describe intervention components is a significant step forward for clarity of intervention content description (Kok et al., 2016; Michie et al., 2013). However, several limitations exist when utilising taxonomies as the BCTTv1 for evidence synthesis and fidelity assessments. To address these limitations, researchers such as Knittle (2015) have called upon the health psychology community to advance reporting of intervention development and evaluation. However, to completely overcome these limitations, this movement needs to be simultaneously instigated in other fields such as medicine, as health psychology research is frequently cross disciplinary (Taylor, 1999).

6.7.3 Strength and limitations of the overall project.

The main premise of this research was to create a better understanding of goal-setting behaviours in a diabetes context. While a significant gap in the literature suggested more research was needed in this area, the topic of goal-setting derived initially from a research prioritisation exercise with diabetes stakeholders (Mc Sharry et al., 2016). As studies suggest that stakeholder involvement can positively impact on the quality and appropriateness of research projects (Brett et al., 2014), the development of shared research priorities has provided a strong rationale for this research The research prioritisation exercise aimed to reach a consensus on target behaviours for research in diabetes in Ireland, and therefore included a wide range of stakeholders such as people with diabetes, HCPs and policy makers. However, it may be possible, that people with diabetes may have felt less comfortable to voice their perspectives as a result of the

possible hierarchy within a HCPs-patient relationship. To reduce social pressure, the survey completion and the ranking of behaviours were conducted anonymously. However, future research could consider the option of having a separate research prioritisation for people with diabetes, to create a stronger voice for service users.

Additionally, as this research focussed on HCP goal-setting behaviour in a diabetes context, exploring HCPs' perspectives on the implementation and operationalisation of goal-setting techniques was prioritised in this project. However, multiple stakeholder perspectives could advance our understanding of goal-setting in this context (Kreuter, De Rosa, Howze, & Baldwin, 2004). Therefore, in a current research project, perspectives surrounding the implementation of goal-setting within DSME and diabetes support are being explored in people with diabetes. However, due to time and resource constraints these perspectives were not included in this thesis, which could be considered a limitation of this PhD.

This PhD used a mix of qualitative and quantitative research methods. Using a mixed method approach can create a more complete understanding of a complex problem as it obtains complementary views, and generates more detail than could be gained from using either method exclusively (McEvoy & Richards, 2006). Overall, each study addressed the similar aim of creating a better understanding of goal-setting behaviours in a diabetes context. A certain level of data connection took place between studies as information collected in each study informed the data collection and interpretation of subsequent studies. Furthermore, the qualitative work of study 3 aimed to provide a deeper understanding of the quantitative fidelity findings of study 2. However, the three studies were completed in a sequential manner, meaning that the studies were completed in a sequence with data collection of one study followed by

another (Creswell, Klassen, Plano Clark, & Smith, 2011). Full integration of findings was thus limited and mainly occurred in the final phase of this PhD project. Additionally, each study was disseminated as a standalone piece of research. This approach limited the integration of data and results which is typically recommended for mixed methods research (Creswell et al., 2011; Yardley & Bishop, 2015).

Finally, while goal-setting was chosen as a priority HCP behaviour for research in both T1DM and T2DM in the research prioritisation, understanding the implementation of goal-setting in T1DM was prioritised in this project. However, when developing our evidence base, nearly all studies included in the systematic review focussed on T2DM. While drawing information from research conducted in the areas of both T1DM and T2DM was valuable to assess the overall effectiveness of goal-setting strategies in a diabetes context, one could question the generalisability of the systematic review finding to the area of T1DM. While subsequent studies in this project have created a better understanding of the implementation of goal-setting strategies in T1DM care and education, future intervention research should focus on assessing the effectiveness of goal-setting strategies in the area of T1DM.

6.8 Conclusion

This research has significantly advanced our understanding of the effectiveness and implementation of goal-setting techniques in a diabetes context. The findings from this research suggest that integrating goal-setting within diabetes support is beneficial and should be recommended. However, while goal-setting in diabetes support seems advisable, the current implementation of these strategies could be optimised. Additionally, the findings from this research show that even when goal-setting

techniques are structurally and consistently included in programmes, implementation issues can still arise. Therefore, when promoting HCPs' goal-setting behaviours in future diabetes support, this research proposes that several implementation barriers should be addressed. Continuously monitoring implementation fidelity, optimising HCPs' training and promoting more positive attitudes towards the operationalisation of goal-setting strategies are advisable in future research and practice. Additionally, the involvement of psychologists or behaviour change experts could advance future implementation of goal-setting techniques in a diabetes context.

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8. Appendices

8.1 Appendix I: Research prioritisation paper.

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Research Involvement and Engagement

CrossMark

Prioritising target behaviours for research in diabetes: Using the nominal group technique to achieve consensus from key stakeholders

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Plain English summary

The behaviour of people with diabetes (e.g. taking medication) and the behaviour of doctors and other healthcare professionals (e.g. checking patients' blood sugar) are important. Our research group wanted to select one patient behaviour and one healthcare professional behaviour as topics to research in Ireland. Patients and healthcare professionals are not usually asked to help decide on research topics. In this study, we wanted to bring together patients, healthcare professionals and policy makers to help us decide on the most important target behaviours for research in diabetes in Ireland. We worked with 24 participants, including people with diabetes, diabetes healthcare professionals and policy makers. First, participants suggested behaviours they thought were important to target for research in diabetes. Participants then attended

a meeting and ranked which of the behaviours were the most important and discussed the results of the rankings as a group. We identified the most highly ranked patient and healthcare professional behaviours. The top ranked behaviour for people with Type 1 diabetes was to ‘take insulin as required’ and for people with Type 2 diabetes was to ‘attend and engage with structured education programmes’. ‘Engage in collaborative goal setting with patients’ was the top ranked behaviour for healthcare professionals. Our study shows it is possible for researchers to work with people with diabetes, healthcare professionals and policy makers to decide on research topics. The top ranked behaviours will now be researched by our group in Ireland.

Abstract

Background. Working with patients, healthcare providers, and policy makers to prioritise research topics may enhance the relevance of research and increase the likelihood of translating research findings into practice. The aim of the present study was to work with key stakeholders to identify, and achieve consensus on, the most important target behaviours for research in diabetes in Ireland

Methods. Twenty-four participants, including people with diabetes, diabetes healthcare professionals and policy makers, took part in a nominal group technique consensus process. Through an online survey, participants generated lists of important target behaviours in three areas: managing Type 1 diabetes, managing Type 2 diabetes and preventing Type 2 diabetes. Participants then attended a research prioritisation meeting and ranked target behaviours in two rounds, with group discussion between ranking rounds. For each of the three key areas, the six top ranked behaviours relevant to people with diabetes and healthcare professionals were identified.

Results. In most cases, the most highly ranked behaviour was the same for Ranking 1 and Ranking 2 and consensus increased in relation to endorsement of top ranked

behaviours. However, some behaviours did change position between rankings. The top behaviour relevant to people with Type 1 diabetes was ‘taking insulin as required’ and for people with Type 2 diabetes was ‘attending and engaging with structured education programmes’. ‘Engage in collaborative goal setting with patients’ was the top ranked behaviour relevant to healthcare professionals for managing both Type 1 and Type 2 diabetes. For preventing Type 2 diabetes, 'engage in healthy behaviours as a family' was the highest ranked population behaviour and ‘attend and engage with behaviour change training’ was the highest ranked professional behaviour.

Conclusion. It is possible to work with a diverse group of stakeholders to inform the diabetes research agenda. The priorities identified were co-produced by key stakeholders, including patients, healthcare professionals and policy makers, and will inform the development of a programme of behavioural research in diabetes in Ireland. The study also provides a worked example of a research prioritisation process using the nominal group technique, and identified limitations, which may be useful for other researchers.

Keywords: Diabetes, Research prioritisation, Public and patient involvement, Research engagement, Behaviour change, Intervention development

Background

There is strong evidence that changing people’s health-related behaviour can impact the leading causes of mortality and morbidity [1]. Behaviour change is central in the treatment of chronic illness, and targeting behaviours to prevent and manage chronic illnesses is imperative to deal effectively with increasing numbers of patients and escalating costs [2]. Recent examples of successful interventions have targeted both the

behaviour of people with diabetes (diet and activity behaviours) and healthcare professional behaviour (early intervention for diabetes foot ulcers) [3, 4]. Changing behaviour can improve outcomes, with increasing evidence that interventions targeting behaviour change in diabetes can be effective [5, 6].

Despite the potential for behaviour change to improve diabetes outcomes, developing effective interventions is challenging. Diabetes management is complex, encompassing many different behaviours, and patients often struggle to make and maintain the behavioural changes required to manage their condition [7]. As this programme of behavioural research within diabetes continues to grow, how should we decide which behaviours should be prioritised for research? It has been suggested that much health-related research does not address topics which are of importance to patients and clinicians [8]. Seeking the views of patients and healthcare providers should be an essential part of determining the behavioural research agenda, especially to ensure impact from publicly-funded research [9].

Changing diabetes care to implement evidence from research into routine practice is a major challenge within the constraints of the healthcare system [10–12]. Within diabetes, attempts have been made to reduce the research-evidence gap with initiatives such as the Bringing Research in Diabetes to Global Environments and Systems (BRIDGES) project supporting the development of interventions that can be adopted and disseminated in real world settings [13]. Qualitative work with BRIDGES project researchers pinpointed lack of stakeholder and diabetes community links as key barriers in the implementation of diabetes research [14]. Despite the identified need to increase stakeholder engagement, there are few published examples of methods to involve stakeholders in the research process in diabetes.

More recently, efforts have been made to involve stakeholders in the research process by seeking input from patients and healthcare professionals in the prioritisation of research. One approach to collaborative research prioritisation has been driven by the James Lind Alliance which provides guidance on the development of Priority Setting Partnerships [15]. The James Lind Alliance Priority Setting Partnerships aim to bring patient and clinicians together to prioritise treatment uncertainties for research. Treatment uncertainties have been identified and ranked for a range of conditions [16] including Type 1 diabetes [17].

The first step in James Lind Alliance Priority Setting Partnerships is to identify potential research questions of interest to patients and providers. However, involving service users solely in the prioritisation of research questions can be limiting, with evidence that patient suggestions frequently fail to meet the criteria of a researchable question [18]. In addition, focusing solely on treatment uncertainties can limit the scope of research prioritisation. Research exploring the translation of evidence-based behaviour change interventions into practice, for example, does not fall within the treatment uncertainty remit.

The aim of our research prioritisation was to move beyond a more narrow discussion of treatment uncertainties to identify and achieve consensus on shared priority areas for research in diabetes in Ireland. Both the Delphi and nominal group technique processes have been used for the development of consensus in health services research. We also wanted to increase engagement in our programme of research and to build links with relevant stakeholders in Ireland, and so the anonymous approach associated with the Delphi technique was not appropriate to our aims.

The nominal group technique is a controlled group process for the generation and ranking of ideas and for consensus development [19]. The nominal group technique

generates a high number of ideas and includes social interaction and discussion while limiting normative pressure for conformity through the use of private individual ranking [19]. Each participant in a nominal group technique process has an equal private ranking vote which provides a democratic process to navigate mismatches between researcher, patient, provider and policy maker priorities [15]. The nominal group technique also avoids limiting patients' contribution to priority setting by not requiring priorities to be articulated in the form of a researchable question [18].

The aim of the present study was to engage in a nominal group technique process- with key stakeholders to identify, and achieve consensus on, the most important target behaviours for research in diabetes in Ireland. By identifying behaviour change targets that address the needs of the diabetes community, we hoped to enhance the relevance of our programme of research to the Irish healthcare context and to increase the likelihood of future translation of the findings into practice. By focusing on target behaviours rather than tightly defined research questions or treatment uncertainties, we hoped to maximise the potential for patients and healthcare professionals to impact on the development of the research agenda. Finally, by clearly outlining a systematic approach to engaging with key stakeholders we hoped to provide a useful resource for other researchers seeking to engage patients, professionals and policy makers, in the design of research.

The study forms part of a programme of research to develop and evaluate two behavioyr change interventions in diabetes in Ireland: one focusing on a behaviour relevant to people with diabetes, and one on a behaviour relevant to healthcare professionals. In identifying high priority behaviours for research, we focused on three key areas: managing Type 1 diabetes mellitus (Type 1 DM), managing Type 2 diabetes mellitus (Type 2 DM) and preventing Type 2 DM. Within each of these areas, we aimed

to develop a prioritised list of the most highly ranked target behaviours relevant to people with diabetes and healthcare professionals. We aimed to get the views of people with diabetes, healthcare professionals with clinical experience of diabetes and policy makers working in the area of diabetes.

Methods

The nominal group technique (also known as an expert panel) was used to identify, and achieve consensus on, the most important target behaviours for research [20]. The nominal group technique was chosen as a systematic process that facilitates both idea generation and consensus development [19].

Participants.

The nominal group technique is as a small group technique, recommended for use in groups of up to ten participants [19]. Our sample size was informed by a desire to maintain the group dynamic of the technique while still including a range of healthcare professional, patient and policy stakeholders. We set a limit of 25 total participants, to allow for manageable group feedback and discussion as part of the nominal group technique process. Participants were sampled purposively to represent the following groups: people with Type 1 DM and Type 2 DM, healthcare professionals with clinical experience of diabetes and policy makers working in the area of diabetes. Potential healthcare professional and policy maker participants were identified through peer consultation. Those who declined were asked to nominate an alternative in their place. People with diabetes were informed of the study through a flyer circulated through Diabetes Ireland, a national charity dedicated to supporting people with diabetes. Details of number of patients contacted were not available to the research team. Response was generally enthusiastic, ten patients, and an additional two parents of children with diabetes, contacted the research team. Parents of children with

diabetes were not eligible for participation as the focus of this prioritisation exercise was on adult patients with diabetes. The research team sent on full details of the meeting, including the proposed date, to potential participants and answered any questions. Six of the ten participants were available and attended the meeting. As participants were engaged in public and patient involvement activities and contributing to research design rather than taking part in a research study, ethical approval was not sought.

Procedure.

The nominal group technique begins with eliciting participant views on a topic. Similar suggestions are grouped together and a facilitated group discussion during a structured meeting allows for the clarification and evaluation of items. Each participant then privately ranks each item, the overall rankings are calculated, presented, and discussed and the items are privately re-ranked. The process of achieving consensus through an initial ranking, group discussion, and a second re-ranking was decided in advance and follows published nominal group technique guidance [19]. For the current study, a diabetes research prioritisation (DRP) meeting was organised in Galway, Ireland in October 2014. The study process is shown in Fig. 1 and each of the nominal group stages is outlined further below.

Pre-meeting.

Stage 1: Pre-meeting generation and collation of health professional and patient behaviours. In advance of the DRP meeting, participants completed an online survey to generate lists of behaviours to target for research. Participants were asked to generate three health professional behaviours and three patient behaviours in each of the key diabetes areas (managing Type 1 DM, managing Type 2 DM, and preventing Type 2

DM). The importance of participants' own views was emphasised and specific examples were provided for each category of behaviours.

The survey was administered using the Survey Monkey online tool and sent to participants one month in advance of the DRP meeting; a reminder was sent to all participants a week before the meeting. The research team collated all submitted responses by combining similar behaviours to avoid duplication, creating unique behaviours where original submissions included multiple behaviours and creating total lists of behaviours for each key diabetes area.

DRP meeting.

Stage 2: Further development of lists of health professional and patient behaviours. Participants attended in person at a three hour DRP meeting and joined small group tables of four at random as they arrived. At the start of the meeting, the research team gave a short presentation outlining the format of the meeting and defined key terms. Participants were provided with the pre-generated lists of target behaviours and engaged in small group discussions to identify any additional behaviours. Small group tables included a mix of patients, healthcare professionals and policy makers. Each small group had an opportunity to feedback additional behaviours to the larger group, and these were added to the total lists. Group discussions were chaired by an experienced facilitator who aimed to ensure everyone had an opportunity to speak. This process was done six times during the meeting, for each of the three key diabetes areas (managing Type 1 DM, managing Type 2 DM, and preventing Type 2 DM), first for patient behaviours and then for health professional behaviours (see Fig. 2).

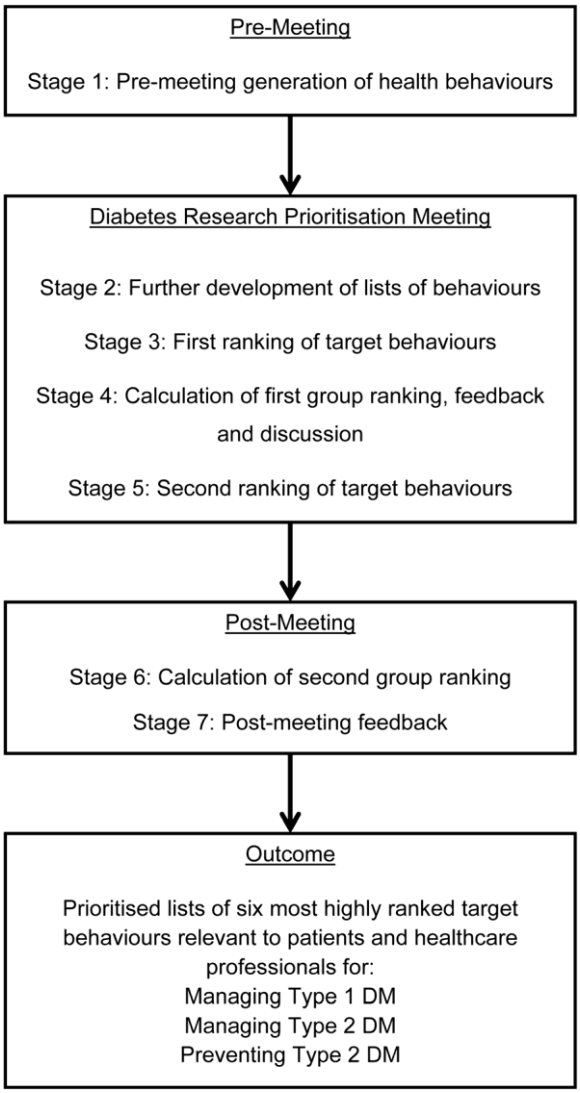

Fig. 1 Diabetes Research Prioritisation Flow Chart

Stage 3: First ranking of target health professional and patient behaviours. Total behaviour lists were presented back to participants on a screen at the front of the room. Participants privately ranked their top six health professional and top six patient behaviours on paper sheets which were collected by members of the research team.

Stage 4: Calculation of first group ranking, feedback and discussion The results of the first ranking were manually entered into an excel spread sheet by members of the research team as the meeting progressed. Data entry was checked for accuracy after the meeting by a second researcher; minimal discrepancies were identified. Top ranked priority behaviours were assigned a score of 6, second ranked behaviours were assigned

a score of 5 and so on. The total scores for each behaviour were calculated and the results were presented back to the group. The six most highly ranked health professional and patient behaviours in each key diabetes area were highlighted. In a group discussion, the facilitator asked participants to comment on the results, particularly focusing on behaviours whose rankings they found surprising or interesting.

14:00	Welcome and introductions	
14:05	Research prioritisation overview Meeting plan	
14:15	Stage 2: Further development of lists of behaviours Stage 3: First ranking of target behaviours	Managing Type 1 DM Managing Type 2 DM Preventing Type 2 DM
15:35	Break and collation of results	
15:50	Stage 4: Calculation of first group ranking, feedback and discussion Stage 5: Second ranking of target behaviours	Managing Type 1 DM Managing Type 2 DM Preventing Type 2 DM
16:50	Next steps Meeting close	

Fig. 2 Diabetes Research Prioritisation Meeting Outline and Timings

Stage 5: Second ranking of target health professional and patient behaviours. Stage 5 followed a similar procedure as Stage 3 and participants were asked to privately re-rank top six health professional and top six patient behaviours on paper sheets in each of the three key areas.

Post meeting.

Stage 6: Calculation of second group ranking. As before, top ranked priority behaviours were assigned a score of 6, second ranked behaviours were assigned a score

of 5 and so on and the total scores for each behaviour were calculated. The number of times each behaviour was ranked in participants' top six and the percentage of participants who ranked each behaviour within their top three priorities were also calculated.

Stage 7: Post-meeting feedback. A summary of the findings was sent to all participants three weeks after the DRP meeting. Participants were sent a link to an online questionnaire and asked to provide feedback on how interesting, enjoyable and useful they found the meeting and to give suggestions as to how the meeting could have been improved.

Results

Participants.

Twenty-four people (10 male, 14 female) participated in the DRP process including hospital and primary care practitioners (*n* = 10), public health practitioners (*n* = 3), people with Type 1 DM (*n* = 3), people with Type 2 DM (*n* = 3), researchers in diabetes (*n* = 2), a policy leader, a patient organisation policy representative and a psychologist involved in diabetes care.

Development of lists of health professional and patient behaviours (Stages 1–2).

Sixteen participants, including seven hospital and primary care practitioners, one public health practitioner, one diabetes researcher, one psychologist, one patient organisation representative and five patients, completed the pre-meeting online task to generate initial behaviour lists. The numbers of behaviours generated through the survey in each of the three key diabetes areas, and the numbers of behaviours following collation and additional item generation during the meeting, are shown in Table 1.

Table 1 Generation of health professional and patient behaviours in advance of, and during, the meeting

Key diabetes area	Total number of behaviours generated at pre-meeting survey	Number of behaviours remaining following collation	Additional behaviours generated during meeting	Final number of behaviours for ranking
Managing Type 1 DM – Patients	37	17	5	22
Managing Type 1 DM – Healthcare Professionals	42	25	7	32
Managing Type 2 DM – Patients	52	26	6	32
Managing Type 2 DM – Healthcare Professionals	47	26	5	31
Preventing Type 2 DM – General Population	46	30	8	38
Preventing Type 2 DM – Healthcare Professionals/ Health Services	48	52	3	55
Total number of behaviours	272	176	34	210

Ranking of health professional and patient behaviours in three key diabetes areas (Stages 3–6).

Table 2 shows the final highest ranked behaviours, for patients and healthcare professionals, in each of the key diabetes areas. Some participants arrived at the meeting late or had to leave early which is reflected in the different numbers of participants reported in Tables 3, 4, 5, 6 and 7. Further details on ranking results are outlined below.

Table 2 Highest ranked patient and health professional behaviours in three key diabetes areas

Key diabetes area	Highest ranked behaviour in Ranking 2
Managing Type 1 DM – Patients	Take insulin as required
Managing Type 1 DM – Healthcare Professionals	Engage in collaborative treatment goal setting with patients
Managing Type 2 DM – Patients	Attend and engage with structured education
Managing Type 2 DM – Healthcare Professionals	Engage in collaborative treatment goal setting with patients
Preventing Type 2 DM – General Population	Engage in healthy behaviours as a family
Preventing Type 2 DM – Healthcare Professionals/Health Services	Attend and engage with behaviour change training

Managing Type 1 DM.

As show in Table 3 for patient behaviours in managing Type 1 DM, 'Take insulin as required' was by far the highest ranked patient behaviour during both Ranking 1 and Ranking 2. Greater consensus for this behaviour was achieved during Ranking 2 when 59.1 % of participants ranked this behaviour in their top three. Interestingly, the second highest ('Take medication as prescribed') and fourth highest ('Quit smoking') behaviours in Ranking 2 did not feature in the top 6 during Ranking 1. For healthcare professional behaviours in managing Type 1 DM, 'Engage in collaborative treatment goal-setting with patients' was the highest ranked behaviour during both Ranking 1 and 2, but showed slightly lower consensus at Ranking 2 (see Table 4).

Table 3 Ranking scores of patient behaviours within the area of managing Type 1 Diabetes Mellitus

Ranking 1 (*N* = 22)					Ranking 2 (*N* = 22)				
Rank	*Behaviours*	*Total score*	*No. of top 6 rankings*	*% of participants with item in top 3*	Rank	*Behaviours*	*Total score*	*No. of top 6 rankings*	*% of participants with item in top 3*
1	Take insulin as required	60	12	40.9	1	Take insulin as required	75	14	59.1
2	Test/monitor blood glucose as often as recommended	41	10	31.8	2	Take medication as prescribed	39	9	31.8
3	Match carbohydrates to insulin daily	37	9	31.8	3	Match carbohydrates to insulin daily + Discussing having diabetes with others	35	8	27.3
							35	8	27.3
4	Attend scheduled appointments and contacts in specialist clinic	34	9	22.7	4	Quit smoking	28	10	13.6
5	Discuss having diabetes with others	30	9	22.7	5	Attend and engage with structured education	28	9	13.6
6	Eat healthily	29	8	22.7	6	Test/monitor blood glucose as often as recommended	27	8	13.6

Table 4 Ranking scores of healthcare professional behaviours within the area of managing Type 1 Diabetes Mellitus

Ranking 1 (*N* = 22)					Ranking 2 (*N* = 22)				
Rank	*Behaviours*	*Total score*	*No. of top 6 rankings*	*% of participants with item in top 3*	Rank	*Behaviours*	*Total score*	*No. of top 6 rankings*	*% of participants with item in top 3*
1	Engage in collaborative treatment goal setting with patients	74	16	59.1	1	Engage in collaborative treatment goal setting with patients	72	16	54.5
2	Provide consultations that empower and motivate service users	44	10	27.3	2	Provide consultations that empower and motivate service users	57	13	40.9
3	Discuss a patient's priorities in diabetes self-management	38	11	27.3	3	Offer structured patient education	54	13	36.4
4	Conduct annual patient screening for diabetes complications	28	9	18.2	4	Discuss a patient's priorities in diabetes self-management	46	12	31.8
5	Provide more flexible services	28	8	18.2	5	Provide more flexible services	37	11	27.3
6	Offer structured patient education	28	8	18.2	6	Conduct annual patient screening for diabetes complications	33	9	18.2

Managing Type 2 DM.

'Attend and engage with structured education' was the highest ranked behaviour during both Ranking 1 and 2, for patient behaviours in managing Type 2 DM. At Ranking 2, there was greater consensus and this behaviour was ranked in the top 3 by 40.9 % of participants as compared to 29.2 % of participants in Ranking 1. 'Monitor your mental health' and 'Set realistic goals for physical activity' featured in the top 6 during Ranking 2 but had not been highly ranked during Ranking 1 (see Table 5).

Healthcare professional behaviours for the management of Type 2 DM was the only category where the top ranked behaviour changed from Ranking 1 to Ranking 2. At Ranking 2, 'Engage in collaborative treatment goal setting with patients' was the top ranked behaviour, a jump from being ranked fifth in Ranking 1. The percentage of

people ranking this behaviour in their top 3 almost doubled from 21.7 % at Ranking 1 to 42.9 % in Ranking 2. ‘Conduct patient-centred consultations, make sure that the patient's needs are addressed instead of the professionals needs’ which was ranked first during Ranking 1 was a close second in Ranking 2. The number of participants ranking this item within their top 3 also increased from Ranking 1 to Ranking 2 (see Table 6).

Table 5 Ranking scores of patient behaviours within the area of managing Type 2 Diabetes Mellitus

Ranking 1 (*N* = 24)					Ranking 2 (*N* = 22)				
Rank	*Behaviours*	*Total score*	*No. of top 6 rankings*	*% of participants with item in top 3*	Rank	*Behaviours*	*Total score*	*No. of top 6 rankings*	*% of participants with item in top 3*
1	Attend and engage with structured education	53	15	29.2	1	Attend and engage with structured education	62	15	40.9
2	Eat healthily	49	10	37.1	2	Increase exercise	45	11	31.8
3	Engage in more self-management strategies	43	12	25	3	Engage in more self-management strategies	42	12	31.8
4	Increase exercise	32	8	16.7	4	Take medication as prescribed	37	12	18.2
						+			
						Monitor your mental health	37	9	27.3
5	Engage in physical activity, at least 30 min 5 days a week	28	6	20.8	5	Eat healthily	35	14	27.3
6	Take medication as prescribed	27	7	16.7	6	Set realistic goals for physical activity	33	8	27.3

Preventing Type 2 DM.

‘Engage in healthy behaviours as a family’ was the top ranked population behaviour to prevent Type 2 DM in both Ranking 1 and Ranking 2. As shown in Table 7, consensus in prioritisation of this behaviour increased in Ranking 2 where it had a higher total score and was ranked in a greater percentage of participants’ top three

behaviours. ‘Reduce sedentary behaviour’ was ranked fourth in Ranking 1 but did not feature in the top six in Ranking 2 and was replaced by ‘Advocate for environmental change to support healthy behaviours’ and ‘Increase cost of sugary foods’.

‘Attend and engage with behaviour change training’ was the highest ranked healthcare professional/health service behaviour at both Ranking 1 and 2. However, there was not as clear a difference between the top ranked behaviour and the second ranked behaviour ‘GPs should use weight charts to estimate BMI of children more and advise parents on the best course of action when a child is at the overweight stage’ as there was in other categories (See Table 8). The remaining behaviours in the top six were the same between Ranking 1 and Ranking 2 albeit in a slightly different order.

Post-meeting feedback (Stage 7)

Fifteen participants, including five hospital and primary care practitioners, two public health practitioners, one diabetes researcher, one psychologist, and four patients completed the post-meeting feedback questionnaire. Two of the respondents did not provide their details. On a scale from 1 to 5, the mean scores for how enjoyable, useful and interesting participants found the meeting were 3.9, 3.6, and 3.9 respectively (where higher scores indicate higher levels of these characteristics). Common suggestions for improvement included increasing the time for discussion, including more patients, and reducing the number of options by using broader umbrella terms to group similar behaviours together.

Table 6 Ranking scores of healthcare professional behaviours within the area of managing Type 2 Diabetes Mellitus

Ranking 1 (*N* = 23)					Ranking 2 (*N* = 21)				
Rank	*Behaviours*	*Total score*	*No. of top 6 rankings*	*% of participants with item in top 3*	Rank	*Behaviours*	*Total score*	*No. of top 6 rankings*	*% of participants with item in top 3*
1	Conduct patient centred consultations, make sure that the patient's needs are addressed instead of the professionals needs	48	12	30.4	1	Engage in collaborative treatment goal setting with patients	57	14	42.9
2	Engage at policy level	45	12	30.4	2	Conduct patient centred consultations, make sure that the patient's needs are addressed instead of the professionals needs	51	12	38.1
3	Offer weight management/ lifestyle modification educational programmes	44	12	30.4	3	Regularly assess patients medication, make sure patients are on optimal doses	47	14	28.6
4	Use a proactive preventative approach	43	9	30.4	4	Offer weight management/ lifestyle modification educational programmes	43	11	38.1
5	Engage in collaborative treatment goal setting with patients	37	10	21.7	5	Use a proactive preventative approach	42	11	33.3
6	Conduct an annual examination of all people with Type 2 Diabetes their feet, legs and hypertension	34	10	17.4	6	Conduct an annual examination of all people with Type 2 Diabetes their feet, legs and hypertension	38	8	33.3
	+					+			
	Set more individual goals, relevant to the patient	34	8	26.1		Engage at policy level	38	10	23.8

Table 7 Ranking scores of population behaviours within the area of preventing Type 2 Diabetes Mellitus

Ranking 1 (*N* = 23)					Ranking 2 (*N* = 21)				
Rank	*Behaviours*	*Total score*	*No. of top 6 rankings*	*% of participants with item in top 3*	Rank	*Behaviours*	*Total score*	*No. of top 6 rankings*	*% of participants with item in top 3*
1	Engage in healthy behaviours as a family	50	12	34.8	1	Engage in healthy behaviours as a family	64	13	50.4
2	Increase exercise	29	7	21.7	2	Parental behaviours around diet and exercise for their children	45	11	38.1
3	Parental behaviours around diet and exercise for their children	28	7	21.7	3	Increase exercise	41	10	38.1
4	Reduce sedentary behaviour	26	6	17.4	4	Use smaller cups, bowls and plates to help reduce portion sizes at mealtimes	33	9	19.1
5	Use smaller cups, bowls and plates to help reduce portion sizes at mealtimes	26	7	21.7	5	Advocate for environmental change to support healthy behaviours	25	7	19.1
6	Advocate for compulsory physical education in school	26	6	13	6	Advocate for compulsory physical education in schools	24	7	23.8
						+			
						Increase cost of sugary foods	24	5	19.1

Table 8 Ranking scores of healthcare professional behaviours within the area of preventing Type 2 Diabetes Mellitus

Ranking 1 (*N* = 23)					Ranking 2 (*N* = 18)				
Rank	*Behaviours*	*Total score*	*No. of top 6 rankings*	*% of participants with item in top 3*	Rank	*Behaviours*	*Total score*	*No. of top 6 rankings*	*% of participants with item in top 3*
1	Attend and engage with behaviour change training	38	9	21.7	1	Attend and engage with behaviour change training	43	9	38.9
2	Lobby governments to fund community health programmes	37	9	26.1	2	GPs should use weight charts to estimate BMI of children more and advise parents on the best course of action when a child is at the overweight stage	40	9	44.4
3	Advocate for policy level health behaviour change	36	9	21.7	3	Advocate for policy level health behaviour change	34	8	27.8
4	Set specific targets for physical activity	22	7	17.4	4	Set specific targets for physical activity	28	6	27.8
5	GPs should use weight charts to estimate the BMI of children more and advise parents on the best course of action when a child is at the overweight stage	21	5	13	5	Provide education at schools	24	6	22.2
6	Provide education at schools	20	7	13	6	Lobby governments to fund community health programmes	20	5	16.7

Discussion

This study demonstrates that it is possible to work with a group of diverse stakeholders - people with diabetes, healthcare professionals and policy makers - in a consensus process to co-produce a prioritised list of behaviours to target for intervention research. Key stakeholders are more likely to drive forward the implementation of

research findings for research topics important to them and over which they feel ownership. By engaging with key stakeholders from the outset, we have begun developing strategic alliances with health partners and service users which will be maintained throughout the programme of research.

Utilizing a nominal group process approach resulted in the identification of priorities at a broader level than could have been achieved with a more narrow focus on treatment uncertainties. Attendance and engagement with structured education, for example, would not have been identified as a priority if we had followed the guidance provided for James Lind Alliance Priority Setting Partnerships as evidence on the efficacy of structured education programmes is already available. Our approach allowed stakeholders to identify behaviours where regular performance of the behaviour, rather than treatment uncertainty, is the major problem.

The nominal group process findings indicated that in most cases, the most highly ranked behaviour was the same for Ranking 1 and Ranking 2, suggesting that the discussion and re-ranking process did not significantly change participants' views. However, there were examples where behaviours featured in the top 6 at Ranking 2 but not at Ranking 1, presumably reflecting the impact of suggestions and arguments offered by participants during group discussions. Details of the discussions that might have led to these changes were not recorded, but would make an interesting and useful addition to future nominal group exercises. As expected in a consensus building study, consensus generally increased in relation to endorsement of the most highly ranked behaviours between the first and second rankings.

A number of striking findings emerged in relation to the most highly ranked priorities. For people with Type 1 DM there was general consensus that targeting 'taking insulin as required' is the most important behaviour for research. Indeed, the top

three highest ranked behaviours were related to effectively monitoring and managing blood glucose, by administering insulin and counting carbohydrates. The skills required for people with Type 1 DM to maintain good glucose control are complex and demanding [21]. A number of studies report that glucose control remains unsatisfactory despite close monitoring and participation in educational programmes by many people with Type 1 DM [22], although there is some evidence that training in flexible, intensive insulin treatment can improve glycaemic control [23]. Future research should focus on developing and delivering effective interventions to promote the skills needed by people with Type 1 DM to achieve good glycaemic control.

For people with Type 2 DM, attending and engaging with structured education programmes was most highly ranked. Research into structured education programmes for people with Type 2 DM in Ireland has been lacking, but recent studies have demonstrated the efficacy of structured education in Ireland [24]. However, a significant proportion of people with Type 2 DM are either not offered or do not attend structured education programmes [25]. Future research should focus on ways to engage people with Type 2 DM in education programmes, as well as ensuring that such programmes are as patient-centred as possible to increase the benefits to participants.

Interestingly, behaviours related to collaborative goal setting and patient-centred care were highly ranked. ‘Engage in collaborative treatment goal setting with patients’ was the top ranked healthcare professional behaviour for the management of both Type 1 DM and Type 2 DM. Among people with diabetes, patients’ perceptions of collaborative care (including collaborative goal setting) have been shown to be associated with patients’ reported self-management [26], however, the relationship between collaborative goal setting and clinical control among remains poorly understood [27]. Future research should focus on interventions to promote the use of

collaborative goal setting among healthcare professionals and people with diabetes, and measuring the associated impact on clinical outcomes.

In relation to preventing Type 2 DM, the most highly ranked behaviours were promotion of healthy exercise and diet, with priority given to engaging in healthy behaviours as a family. There is considerable evidence that increased levels of physical activity are related to better clinical outcomes in diabetes, and additional evidence that physical activity interventions are particularly effective when combined with dietary advice [28]. There was much discussion at the meeting around the need to advocate for policy change and attempt to promote environmental change to support healthy behaviour. There is evidence that environmental and policy approaches lead to increases in physical activity [29], and future research should focus on finding ways to maximise the role of behavioural science theory in development and implementation of public health interventions [30].

For healthcare professionals' behaviours to prevent Type 2 DM, the highest ranked behaviour was 'attend and engage with behaviour change training'. Recent trials of behaviour change counselling have found limited effects on behaviour change outcomes [31]. Future research should focus on finding more effective ways to train healthcare professionals to promote behaviour change among their patients.

The current study forms the first step in a behaviour change intervention development process. One behaviour relevant to people with diabetes, and one behaviour relevant to healthcare professionals, will be selected as targets for intervention development. As per recommended guidance [32], the selection of target behaviours will be informed by the comparison of the top behaviours identified in each key area under criteria of the likely impact of changing the behaviour, the likelihood of

change, the potential positive or negative spillover to other behaviours and the ease of measurement of each behaviour.

Limitations

Post-meeting feedback indicated that participants would have liked more time for discussion, although whether this would be best achieved through a longer meeting or additional meetings was unclear. Addressing priorities for both Type 1 DM and Type 2 DM on the same day may have been overly ambitious and at times the research team agreed that the meeting felt rushed. Covering Type 1 DM and Type 2 DM at the meeting reflected an attempt to reduce time and travel burden for participants who had experience of both conditions. More time for discussion might have resulted in slightly different priorities. However, when asked how they found the length of the meeting, one third of participants indicated that the meeting was too long. Finding balance between adequate time for discussion and reducing burden on participants with busy schedules is a challenge and should be considered in future research prioritisation exercises.

The nominal group technique has been recommended for groups no larger than ten people [19]. However, to ensure we addressed a range of stakeholder experiences we included different types of healthcare professionals, as well as patients and policy makers. Including this range required a larger number of participants. This may also have added to the sense of the process being rushed as group feedback took longer than with a smaller number of participants. Future nominal group technique processes that require larger numbers could consider guidance from Cantrill et al. [19] to split the sample into two or more groups and to pool results.

Consensus refers to level of agreement among participants in a given round and stability refers to level of agreement between rounds. We did not decide on a priori levels of agreement and stability required for consensus but instead chose to work

through two ranking rounds within a one day meeting. The degree to which true consensus was reached is not clear, although in general the endorsement of the most highly ranked behaviours increased between the first and second rankings.

Previous discussions on the use of nominal group technique have debated the merits of mixed versus homogenous groups of participants [19, 33]. As our intention was to achieve consensus on the most important target behaviours for research in diabetes in Ireland we included a mix of patients, providers and policy makers, as each of these stakeholders have a role in behaviour change in diabetes. Despite the best efforts of the experienced facilitator, it is possible that patients may have felt less confident in voicing their opinions given the potentially hierarchical nature of provider-patient relationships. However, the initial generation of lists of behaviours and the actual ranking of behaviours were conducted privately to reduce social pressure and to allow the opinion of each participant to be given equal weighting.

Our nominal group technique process also lacks the representativeness that might be achieved with a large random sample. The overall number of participants was relatively small and, although we purposively sampled for diversity of expertise and experience, the views cannot be claimed to be nationally representative. The views of the 24 stakeholders who took part may not be typical of such a widespread condition and could not be expected represent all possible priorities. In particular, we felt it would have been beneficial to include more people with diabetes, as experiences can vary widely between individuals. Previous studies using the nominal group technique have found participants' views to be an adequate representation of the views of the wider community [34]. However, these studies used the nominal group technique with healthcare professionals; as our process included healthcare professionals, patient and policy makers we cannot claim the 24 included participants were representative of each

of these groups. Finally, the current study describes research priorities identified within the Irish health system, and caution should be used when generalising as priorities vary according to health system context [35].

Conclusion

To impact, and improve, health and healthcare, behavioural researchers need to engage with stakeholders outside of the research community. In the current study, we have demonstrated that it is possible to engage people with diabetes, healthcare professionals and policy makers working in the area of diabetes to generate and prioritise behavioural research topics. The priorities identified were co-produced by key stakeholders, including patients, healthcare professionals and policy makers, and will inform the development of a programme of behavioural research in diabetes in Ireland. We will continue to engage with these stakeholders by inviting patients, professionals and policy makers to sit on steering committees to move chosen priorities forward. The study also provides a worked example of a research prioritisation process using the nominal group technique which may be a useful for other researchers.

Abbreviations

DRP: Diabetes research prioritisation;

Type 1 DM: Type 1 Diabetes Mellitus;

Type 2 DM: Type 2 Diabetes Mellitus.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

JMS participated in the design and coordination of the study and helped to draft the manuscript. MF and LH entered data, participated in the coordination of the study and provided comments on the study manuscript. MB conceived of the study,

participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

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8.2 Appendix II: PRISMA Checklist Study 1

Section/topic	#	Checklist item	Page number in manuscript
TITLE			0
Title	1	Identify the report as a systematic review, meta-analysis, or both.	0
ABSTRACT			1
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.	1
INTRODUCTION			2
Rationale	3	Describe the rationale for the review in the context of what is already known.	2
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			6
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.	6
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.	6
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.	7
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1
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).	7
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.	8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	8
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.	9

Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	9
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.	9
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).	9
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	9
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.	10
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.	11
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).	12
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.	12
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	12
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	12
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	15
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).	16
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).	18
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	19
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.	21

8.3 Appendix III: Search strategies Study 1

Medline (ovid) search strategy

1	Diabetes$.mp.
2	IDDM.mp.
3	NIDDM.mp.
4	Mody.mp.
5	Glyc?emic$.mp.
6	“Insulin dependent”.mp.
7	“non-insulin dependent”.mp
8	HbA1c$.mp.
9	Blood glucose.mp.
10	Blood sugar.mp.
11	Hemoglobin A.mp.
12	Glycosylated$.mp.
13	Hypoglyc$.mp.
14	Hypergly$.mp.
15	or/1-14
16	Goal$.mp.
17	Goal-setting$.mp.
18	Goal-setting$.mp.
19	Action plan$.mp.
20	Coping plan$.mp.
21	Commitment.mp.
22	Behavi?ral contract.mp
23	(Discrepancy between current behavi?r and goal standard).mp.
24	Review behavi?r goal.mp.
25	Review of outcome goal.mp.
26	or/ 16-25
27	Infant$.mp.
28	Child$.mp.
29	Toddler$.mp.
30	Kids$.mp.
31	Youth$.mp.
32	Teen$.mp.
33	Minor$.mp.
34	Gestation$.mp
35	Pregnan$.mp
36	Insipidus$.mp
37	or/27-36
38	15 and 26
39	**38 not 37**
40	**limit 39 to English language**

Psychinfo (ovid) search strategy

1	Diabetes$.mp.
2	IDDM.mp.
3	NIDDM.mp.
4	Mody.mp.
5	Glyc?mic$.mp.
6	“Insulin dependent”.mp.
7	“non-insulin dependent”.mp
8	HbA1c$.mp.
9	Blood glucose.mp.
10	Blood sugar.mp.
11	Hemoglobin A.mp.
12	Glycosylated$.mp.
13	Hypoglyc$.mp.
14	Hypergly$.mp.
15	or/1-14
16	Goal$.mp.
17	Goal-setting$.mp.
18	Goal-setting$.mp.
19	Action planning.mp.
20	Coping planning.mp.
21	Commitment.mp.
22	Behavi?ral contract.mp
23	Discrepancy between current behavi?r and goal standard.mp.
24	Review behavi?r goal.mp.
25	Review of outcome goal.mp.
26	or/ 15-25
27	Infant$.mp.
28	Child$.mp.
29	Toddler$.mp.
30	Kids$.mp.
31	Youth$.mp.
32	Teen$.mp.
33	Minor$.mp.
34	Gestation$.mp
35	Pregnan$.mp
36	Insipidus$.mp
37	or/27-36
38	15 and 26
39	**38 not 37**
40	**limit 39 to English language**

CINAHL (EBSCO) search strategy

1	**S1** Diabetes*
2	**S2** IDDM
3	**S3** NIDDM
4	**S4** Mody
5	**S5** Glycaemic*
6	**S6** Glycemic*
7	**S7** "Insulin dependent"
8	**S8** "non-insulin dependent"
9	**S9** HbA1c*
10	**S10** Blood glucose
11	**S11** Blood sugar
12	**S12** Hemoglobin A
13	**S13** Glycosylated*
14	**S14** Hypoglyc*
15	**S15** Hypergly*
16	**S16** S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR
17	S14 OR S15
18	**S17** Goal*
19	**S18** Goal-setting*
20	**S19** Goal-setting*
21	**S20** Action plan*
22	**S21** Coping plan*
23	**S22** Commitment
24	**S23** Behavi#ral contract
25	**S24** Discrepancy between current behavi#r and goal standard
26	**S25** Review behavi#r goal
27	**S26** Review of outcome goal
28	**S27** S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26
29	**S28** Infant*
30	**S29** Child*
31	**S30** Toddler*
32	**S31** Kids*
33	**S32** Youth*
34	**S33** Teen*
35	**S34** Minor*
36	**S35** Gestation*
37	**S36** Pregnan*
38	**S37** Insipidus*
39	**S38** S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37
40	**S39** S16 and S27
41	**S41 limit 40 to English language**

PubMed search strategy

1	**#1** Diabetes*
2	**#2** IDDM
3	**#3** NIDDM
4	**#4** Mody
5	**#5** Glycaemic*
6	**#6** Glycemic*
7	**#7** "Insulin dependent"
8	**#8** "non-insulin dependent"
9	**#9** HbA1c*
10	**#10** Blood glucose
11	**#11** Blood sugar
12	**#12** Hemoglobin A
13	**#13** Glycosylated*
14	**#14** Hypoglyc*
15	**#15** Hypergly*
16	**#16** #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15
17	**#17** Goal*
18	**#18** Goal-setting*
19	**#19** Goal-setting*
20	**#20** Action plan
21	**#21** Action planning
22	**#22** Coping planning
23	**#23** Coping plan
24	**#24** Commitment
25	**#25** Behavioral contract
26	**#26** Behavioural contract
27	**#27** Discrepancy between current behavior and goal standard
28	**#28** Discrepancy between current behaviour and goal standard
29	**#29** Review behavior goal
30	**#30** Review behaviour goal
31	**#31** Review of outcome goal
32	**#32** #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR#28 OR #29 OR #30 OR #31
33	**#33** Infant*
34	**#34** Child*
35	**#35** Toddler*
36	**#36** Kids*
37	**#37** Youth*
38	**#38** Teen*
39	**#39** Minor*
40	**#40** Gestation*
41	**#41** Pregnan*
42	**#42** Insipidus*
43	**#43** #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42
44	**#44** #16 and #32
45	**#45 #44 NOT #43**
46	**#46 limit 45 to English language**

Embase search strategy

1	**#1** Diabetes*
2	**#2** IDDM
3	**#3** NIDDM
4	**#4** Mody
5	**#5** Glyc?mic*
6	**#6** “Insulin dependent”
7	**#7** “non-insulin dependent”
8	**#8** HbA1c*
9	**#9** Blood glucose
10	**#10** Blood sugar
11	**#11** Hemoglobin A
12	**#12** Glycosylated*
13	**#13** Hypoglyc*
14	**#14** Hypergly*
15	**#16** #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15
16	**#16** Goal*
17	**#17** Goal-setting
18	**#18** Goal-setting
19	**#19** Action plan
20	**#20**Action planning
21	**#21** Coping planning
22	**#22** Coping plan
23	**#23** Commitment
24	**#24** Behavio?ral contract
25	**#25** Discrepancy between current behavi?r and goal standard
26	**#26** Review behavio?r goal
27	**#27** Review of outcome goal
28	**#32** # 16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27
29	**#29** Infant*
30	**#30** Child*
31	**#31** Toddler*
32	**#32** Kids*
33	**#33** Youth*
34	**#34** Teen*
35	**#35** Minor*
36	**#36** Gestation*
37	**#37** Pregnan*
38	**#38** Insipidus*
39	**#39** ##29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38
40	**#40** #16 and #32
41	**#41 #40 NOT #39**

*Limit: English language

8.4 Appendix IV: Data extraction form Study 1

Name of reviewer:

Date:

Study reference:

1. Study design

Design	Tic box when appropriate
Randomised control trial	
Nonrandomized controlled trials	
Pre-test post-test single group design	

2. Intervention description
Based on the WIDER Recommendation to improve reporting of BCT

Detailed description of interventions in published papers

2.1 Characteristics of those delivering the intervention (e.g practices/ GPs)

Number of providers/ practices

2.2 Characteristics of recipients

Patient characteristics	Reported patient characteristics	Measured by
Age: Mean (SD):		
Gender: (% male)		
Ethnicity:		
Diabetes type (T1DM percentage)		
Diabetes type (T2DM percentage)		
Baseline Mean HbA1c		
Baseline % on insulin		
Baseline mean levels of Hypoglycemic episodes		
Baseline mean levels of Hyperglycemic episodes		
Baseline Physical Activity Levels		
Mean levels of self-care behaviours		
Other characteristics		
Excluded if:		

2.3 The setting

Setting of the intervention	Tick box if appropriate
Medical setting (including rehabilitation and primary care centers	
University	
Grade school	
Fitness facility	
Community center	
Participants' homes	
Other	Specify:
Not specified	

2.4 The mode of delivery

Mode of delivery	Tick box if appropriate
In person	
Via technology (text messaging, internet program)	
Multiple methods' (e.g., in person and via text messaging)	
Other	Specify:
Unclear	

2.5 The intensity (e.g., contact time)

2.6 The duration (in months)

2.7 Adherence/ fidelity to delivery protocols (in percentage)

2.8 Detailed description of the intervention content provided for each study group

3. Clarification of assumed change process and design principles

3.1 The intervention development (eg was the intervention design informed by theoretical considerations)

3.2 The behavioral change techniques used in the intervention

This study focusses on the goal setting/ action planning and Feedback and monitoring clusters

	Description of each BCT utilised						
BCT number	Cluster	BCT	Present? Y or N	Was it reported as a BCT? Y or N	Presence ++ BCT present beyond all reasonable doubt + in all probability blank-none	Number of times BCT was utilised	Provide added information on how the BCT was presented
1.1	Goals and planning	Goal setting (behavior)					
1.2		Problem solving					-
1.3		Goal setting (outcome)					
1.4		Action planning					
1.5		Review behavior goal(s)					
1.6		Discrepancy between current behaviour and goal					
1.7		Review outcome goal(s)					
1.8		Behavioral contract					
1.9		Commitment					
2.1	Feedback and monitoring	Monitoring of behavior by others without feedback					
2.2		Feedback on behaviour					
2.3		Self-monitoring of behaviour					
2.4		Self-monitoring of outcome(s) of behaviour					
2.5		2.5. Monitoring of outcome(s) of behavior without feedback					
2.6		Biofeedback					

2.7		Feedback on **outcome**(s) of behavior					

4. Access to intervention manuals/ Protocols
Are protocols, manuals or supplementary materials available?

YES/ NO

5. Detailed description of active control conditions
Is a control condition available?
If no skip part 5.

As per WIDER recommendations: describe the content of active control groups in as much detail as is possible (e.g., the techniques used) in a similar manner to the description of the content of the intervention itself.

5.1 Characteristics of those delivering the control

Number of people/ practices delivering the control

5.2 Characteristics of the recipients within the control

Patient characteristics	Reported patient characteristics	Measured by
Age: Mean (SD):		
Gender: (% male)		
Ethnicity:		
Diabetes type (T1DM percentage)		
Diabetes type (T2DM percentage)		
Baseline Mean HbA1c		
Baseline % on insulin		
Baseline mean levels of Hypoglycemic episodes		
Baseline mean levels of Hyperglycemic episodes		
Baseline Physical Activity Levels		
Mean levels of self-care behaviours		
Other characteristics		
Excluded if:		

5.3 The setting
Setting for the control condition

5.4 The mode of delivery for the control condition

Mode of delivery	**Tick box if appropriate**
In person	
Via technology (text messaging, internet program)	

Multiple methods' (e.g., in person and via text messaging)	
Other	Specify:
Unclear	

5.5 The intensity in the control condition (e.g., contact time)

5.6 The duration of the control (in months)

5.7 Adherence/ fidelity to delivery protocols within the control (in percentage)

5.8 Detailed description of the intervention content provided for the control condition when available

6. Source of funding:

7. Ethical approval

Yes/ No

8. Quality

The Cochrane Collaboration's tool for assessing risk of bias

Domain		***Entry + Possible bias***	***Judgement Level of risk High/ Low/ Unknown***	***Support for judgement***
Selection bias	1	Random sequence generation *Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence*		(Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.)
	2	Allocation concealment *Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.*		(Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advancee of, or during, enrolment.)
Performance bias	3	Blinding of participants & personnel *Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.*		(Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.)
	4	Blinding of outcome assessment *Detection bias due to knowledge of the allocated interventions by outcome assessors.*		(Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.)
Attrition	5	Incomplete outcome data Follow up of patients/ episodes of care		(Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons

		Attrition bias due to amount, nature or handling of incomplete outcome data.		for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.)
Reporting bias	6	Selective outcome reporting *Reporting bias due to selective outcome reporting.*		(State how the possibility of selective outcome reporting was examined by the review authors, and what was found.)
Other bias	7	*Bias due to problems not covered elsewhere in the table.*		(State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry.)

9. Analysis

Description of outcome measure(s)

Primary/ secondary outcome	**Outcome variable**		**Data collection time points**	**Results**	**Description of how results were measured**
Primary Outcomes:	*Glycaemic control (HbA1c)*				
	Average number of hyperglycaemic episodes				
	Average number of hypoglycaemic episodes				
Secondary outcomes	Self-care behaviours	*carbohydrate counting/ carbohydrate awareness*			
		Insulin dose adjustment			
		Self-monitoring of blood glucose			
		Managing hypoglycaemia			
		Managing equipment and injection sites			
		Accessing health care			
		Physical activity			
	Weight loss				
	Psychological outcomes	*Self- efficacy*			
		Quality of life			
Other outcomes					

8.5 Appendix V: Behavioural change techniques coded within each study

BCT number	Cluster	BCT	Study implementing the BCT	Number of times BCT was utilised within the study (at least)
1.1	Goals and planning	Goal-setting (behavior)	Anderson et al., 2010	1
			Anderson et al., 2009	1
			Clark et al., 2004	1
			Estabrooks et al., 2005 & Glasgow, 2004	1
			Glasgow, 2006	1
			Glasgow et al., 1996	1
			Kroese et al., 2014	1
			Naik et al., 2011	1
			Wallace et al., 2009 & DeWalt et al., 2009	1
			Wolever et al., 2010	1
1.2		Problem solving	Anderson et al., 2009	1
			Clark et al., 2004	4
			Estabrooks et al., 2005 & Glasgow et al., 2004	2
			Glasgow, 2006	1
			Glasgow et al., 1996	3
			Thoolen et al., 2007	1
			Kroese et al., 2014	1
			Wallace et al., 2009 & DeWalt et al., 2009	3
1.3		Goal-setting (outcome)	Corser et al., 2007	1
			Naik et al., 2011	1
			Thoolen et al., 2007	1
1.4		Action planning	Clark et al., 2004	1
			Corser et al., 2007	1
			Estabrooks et al., 2005 & Glasgow et al., 2004	2
			Thoolen et al., 2007	1
			Kroese et al., 2014	1
			Naik et al., 2011	2
			Wallace et al., 2009 & DeWalt et al., 2009	1
1.5		Review behavior goal(s)	Anderson et al., 2010	6
			Anderson et al., 2009	1
			Estabrooks et al., 2005 & Glasgow et al., 2004	2
			Naik et al., 2011	1

1.6		Discrepancy between current behaviour and goal	Not coded	
1.7		Review outcome goal(s)	Clark et al., 2004 Glasgow et al., 2006 Glasgow, 1996 Thoolen et al., 2007 Kroese et al., 2014	6 1 2 2 2
1.8		Behavioral contract	Not coded	
1.9		Commitment	Not coded	
2.1	Feedback and monitoring	Monitoring of behavior by others without feedback	Not coded	
2.2		Feedback on behaviour	Not coded	
2.3		Self-monitoring of behaviour	Thoolen et al., 2007 Kroese et al., 2014	1 1
2.4		Self-monitoring of outcome(s) of behaviour	Not coded	
2.5		2.5. Monitoring of outcome(s) of behavior without feedback	Not coded	
2.6		Biofeedback	Anderson et al., 2009 Glasgow et al., 2006 Thoolen et al., 2007 Kroese et al., 2014	1 1 1 1
2.7		Feedback on **outcome**(s) of behavior	Not coded	

8.6 Appendix VI: Centre invitation letter Study 2

Goal-setting in DAFNE study, Invitation Letter

We would like to invite you to participate in the 'goal-setting in DAFNE study'. This study aims to explore how goal-setting is addressed in a standardised diabetes self-management educational programme as DAFNE '. This research is part of a funded PhD by the Health Research Board (HRB) and is being led by Milou Fredrix, PhD Candidate within the Health Behaviour Change Research Group (HBCRG) at the School of Psychology in NUI Galway, in co-operation with Dr. Molly Byrne, Director of the HBCRG, Dr. Jenny McSharry, Assistant Director of the HBCRG and Dr. Sean Dinneen, Head of School of Medicine, NUI Galway. This study has been approved by the Central DAFNE Office UK and has gained ethical approval from the NUI Galway Ethics board.

This study would involve one researcher observing 1-4 DAFNE goal-setting sessions in your clinic, depending on the amount of courses offered. Thank you for taking the time to read about our study, and we look forward to your response.

Best wishes,

Milou Fredrix (PhD Candidate)
Health Behaviour Change Research Group
G042 AMBE | School of Psychology
National University of Ireland, Galway

NUI Galway
OÉ Gaillimh

HEALTH BEHAVIOUR CHANGE
RESEARCH GROUP

Goal-setting in DAFNE study
Information Sheet

Why is this study being conducted?

The DAFNE programme has become part of routine diabetes care in Ireland. Unfortunately, research shows that DAFNE sometimes fails to help participants instil key self-management practices into their lives on a long term basis.

A core component of DAFNE is goal-setting. Goal-setting techniques can effectively change behaviours if done properly. However, little is known about how exactly the goal-setting component of DAFNE is delivered and received. To improve our knowledge of goal-setting techniques, and to further implement or improve DAFNE, putting this goal-setting component under a microscope could be beneficial.

Who is conducting this study?

The principal investigator for this study is Milou Fredrix, PhD Candidate within the Health Behaviour Change Research Group (HBCRG) at School of Psychology in NUI Galway. This research is part of a PhD project funded by the Health Research Board (HRB) and being conducted in co-operation with Dr. Molly Byrne, Director of the HBCRG, Dr. Jenny McSharry, Assistant Director of the HBCRG and Dr. Sean Dinneen, Head of School of Medicine, National University of Ireland, Galway.

Why have I been contacted?

Five randomly selected diabetes centres within the Republic of Ireland have been contacted.

What does participation in this study mean for my centre?

This study will involve an observation of 1-2 DAFNE goal-setting sessions (depending on the number of DAFNE courses taking place in your centre). This observation will include one researcher observing session 18: goal-setting and part of session 21: action planning. Combined these sessions take around an hour and often take place on the last day of the DAFNE course. The DAFNE course will in no way be interrupted or altered as it will merely be an observation of one component of an existing course. The session will be audio recorded and transcribed.

Will the privacy of staff and patients be protected?

Yes! Patients and educators involved in the course will be asked to give informed consent for the audio recordings. In addition to this, in any report or publication of the study findings, individual centres, their staff, or their patients will not be identified. All information provided as part of the study will be treated as confidential and recordings will be anonymised.

What if I would like more information?

You can contact the researcher or the researcher's supervisor to request more information using the following details:

Principal investigator: Milou Fredrix G042 AMBE | School of Psychology National University of Ireland, Galway E: m.fredrix1@nuigalway.ie T: +353 85 834769	Research Supervisor: Dr. Molly Byrne 1043 AMBE | School of Psychology National University of Ireland, Galway E: molly.byrne@nuigalway.ie T: + 353 91 495182

8.7 Appendix VII: Information letter and consent form (DAFNE participants)

Study 2

ELM PARK, DUBLIN 4
Department of Endocrinology & Diabetes Mellitus

PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE:

GOAL SETTING IN DAFNE: CONTENT AND DELIVERY OF THE GOAL SETTING COMPONENT IN A TYPE 1 DIABETES EDUCATIONAL PROGRAMME.

NAME OF PRINCIPAL INVESTIGATOR: Dr. Ronan Canavan, Department of Endocrinology

You are being invited to participate in a research study. Thank you for taking time to read this.

WHAT IS THE PURPOSE OF THIS STUDY?

The aim of the study is to find out more about how goal setting is being addressed in DAFNE. We are especially interested in how well the goal-setting session in DAFNE is delivered and received in practice.

WHY HAVE I BEEN CHOSEN?

You have been chosen based on your participation in the DAFNE programme.

WHAT WILL HAPPEN IF I VOLUNTEER?

By signing the consent form, you give permission for one DAFNE group-session to be audio recorded. This session will take around 30-45 minutes and is part of the standard DAFNE curriculum. The session will take place within the hospital in the DAFNE course room, on either Thursday or Friday. If you agree to participate, this session will be audio-recorded. The content of this audio-recording will be transcribed after the session.

ARE THERE ANY BENEFITS FROM MY PARTICIPATION?

You will not benefit directly from taking part in this study but the information we will obtain may provide further knowledge of the workings of DAFNE.

ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?

The anticipated risks within this study merely exist around data confidentiality. However, to avoid the risk of someone accessing the audio-files, audio recordings will be safely secured on password protected computer files, and any devises used in this study will be encrypted.

WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?

If you do not agree to partake in the study, your treatment will not be affected in any way. If you do not agree to an audio-recording, the session will not be audio-recorded. If you choose not to be recorded, you can still take part in the goal-setting session. In this case, the session will merely be observed by the researcher.

CONFIDENTIALITY

The content of this audio-recording will be transcribed. While the original recording could possibly identify you, names and hospital names will be replaced by participant numbers and aliases during data transcription, meaning that information cannot be traced back to you. The original recording and any

written material will be stored safely within the University of Galway and will only be accessible by the research team for 5 years. The audio-recording will be used for the purpose of this research only. You or the hospital will not be personally identified in this research.

COMPENSATION

Your doctors are adequately insured by virtue of their participation in the clinical indemnity scheme.

No paid compensation will be given for participation in this study.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?

This study is organised and funded by the Health Research Board Ireland.

HAS THIS STUDY BEEN REVIEWED BY AN ETHICS COMMITTEE?

The St. Vincent's Healthcare Group, Ethics and Medical Research Committee have reviewed and approved this study.

CONTACT DETAILS

For further information about this study, please contact:

Milou Fredrix

Email: m.fredrix1@nuigalway.ie

T: +353 85 8304769

Molly Byrne:

Email: molly.byrne@nuigalway.ie

T: + 353 91 495182

RESEARCH PARTICIPANT'S RIGHTS

If you have any questions about your rights as a research participant, then you may contact the Hospital's Quality & Patient Safety Department 01 2214013

PLEASE TICK YOUR RESPONSE IN THE APPROPRIATE BOX

- I have read and understood the Participant Information YES ☐ NO ☐
- I have had the opportunity to ask questions and discuss the study YES ☐ NO ☐
- I have received satisfactory answers to all my questions YES ☐ NO ☐
- I have received enough information about this study YES ☐ NO ☐
- I understand that I am free to withdraw from the study at any time without giving a reason and without this affecting my future medical care YES ☐ NO ☐
- I agree to take part in the study YES ☐ NO ☐

Participant's Signature: _____ Date: _____

Participant's Name in print: _____

Investigator's Signature: _____ Date: _____

Investigator's Name in print: _ _____

8.8 Appendix VIII: Information letter and consent form (DAFNE educators)

Study 2

ELM PARK, DUBLIN 4
Department of Endocrinology & Diabetes Mellitus

PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE:

GOAL SETTING IN DAFNE: CONTENT AND DELIVERY OF THE GOAL SETTING COMPONENT IN A TYPE 1 DIABETES EDUCATIONAL PROGRAMME.

NAME OF PRINCIPAL INVESTIGATOR: Dr. Ronan Canavan, Department of Endocrinology

You are being invited to participate in a research study. Thank you for taking time to read this.

WHAT IS THE PURPOSE OF THIS STUDY?

The aim of the study is to find out more about how goal setting is being addressed in DAFNE. We are especially interested in how well the goal-setting session in DAFNE is delivered and received in practice.

WHY HAVE I BEEN CHOSEN?

You have been chosen because you are delivering a DAFNE course.

WHAT WILL HAPPEN IF I VOLUNTEER?

By signing the consent form, you give permission for one DAFNE group-session

to be audio recorded. This session will take around 30-45 minutes and is part of the standard DAFNE curriculum. The session will take place within the hospital in the DAFNE course room on either Thursday or Friday. If you agree to participate, this session will be audio-recorded. The content of this audio-recording will be transcribed after the session.

ARE THERE ANY BENEFITS FROM MY PARTICIPATION?

You will not benefit directly from taking part in this study but the information we will obtain may provide further knowledge of the workings of DAFNE.

ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?

The anticipated risks within this study merely exist around data confidentiality. However, to avoid the risk of someone accessing the audio-files, audio recordings will be safely secured on password protected computer files, and any devises used in this study will be encrypted.

WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?

Your participation in this study is completely voluntary. If you do not want the group session to be recorded for any reason, you simply do not sign the consent form.

CONFIDENTIALITY

The content of this audio-recording will be transcribed. While the original recording could possibly identify you, names and hospital names will be replaced by participant numbers and aliases during data transcription, meaning that information cannot be traced back to you. The original recording and any written material will be stored safely within the University of Galway and will only be accessible by the research team for 5 years. The audio-recording will be used for the purpose of this research only. You or the hospital will not be personally identified in this research.

COMPENSATION.

No paid compensation will be given for participation in this study.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?

This study is organised and funded by the Health Research Board Ireland.

HAS THIS STUDY BEEN REVIEWED BY AN ETHICS COMMITTEE?

The St. Vincent's Healthcare Group, Ethics and Medical Research Committee have reviewed and approved this study.

CONTACT DETAILS

For further information about this study, please contact:

Milou Fredrix

Email: m.fredrix1@nuigalway.ie

T: +353 85 8304769

Molly Byrne:

Email: molly.byrne@nuigalway.ie

T: + 353 91 495182

RESEARCH PARTICIPANT'S RIGHTS

If you have any questions about your rights as a research participant, then you may contact the Hospital's Quality & Patient Safety Department 01 2214013

PLEASE TICK YOUR RESPONSE IN THE APPROPRIATE BOX

- I have read and understood the Participant Information YES ☐ NO ☐
- I have had the opportunity to ask questions and discuss the study YES ☐ NO ☐
- I have received satisfactory answers to all my questions YES ☐ NO ☐
- I have received enough information about this study YES ☐ NO ☐
- I understand that I am free to withdraw from the study at any time without giving a reason and without this affecting my future medical care YES ☐ NO ☐
- I agree to take part in the study YES ☐ NO ☐

Participant's Signature: _____ Date: _____

Participant's Name in print: _____

Gender: _____

Age: _____

Investigator's Signature: _____ Date: _____

Investigator's Name in print: _____

8.9 Appendix IX: Study 2 Fidelity scores for all observations per session type

Table 1.

Fidelity scores for session 18 (goal-setting theory session), calculated per BCT and per observation

Session 18	**Number of times BCT was coding in the manual**	**Total no. of times BCT was delivered per observation (calculated fidelity score per BCT)**											**Total number of times BCT expected to be delivered for 100% fidelity)**	**Overall fidelity score per BCT in %**
		obs1	**obs2**	**obs3**	**obs4**	**obs5**	**obs6**	**obs7**	**obs8**	**Obs 9**	**Obs 10**	**Total**		
Goal setting (behaviour)	1	0 (0)	0 (0)	0.5 (.5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0.5	10	.5%
Problem solving	4	1 (.25)	3 (.75)	3 (.75)	2 (.5)	2 (.5)	4 (1)	0.5 (.13)	2 (.5)	1 (.25)	3 (.75)	21.5	40	53.8%
Goal setting (outcome)	1	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	4	10	40%
Action planning	7	3.5 (.5)	1 (.14)	4.5 (.64)	4 (.57)	4 (.57)	1 (.14)	1.5 (.21)	4.5 (.64)	3 (.43)	1.5 (.21)	28.5	70	40.7%
Social support (unspecified)	2	0 (0)	0 (0)	1 (.5)	0 (0)	0 (0)	2 (1)	0 (0)	1.5 (.75)	1 (.5)	1 (.5)	6.5	20	32.5%
Instruction on how to perform the behaviour	1	0 (0)	0 (0)	0 (0)	1(1)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	1 (1)	4	10	40%
Credible source	4	3 (.75)	2.5	0.5 (.13)	4 (1)	2 (.5)	2.5 (.63)	2 (.5)	4 (1)	3 (.75)	3 (.75)	26.5	40	66.3%
Non-specific incentive	1	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0.5 (.5)	0 (0)	2.5	10	25%
Self-incentive	1	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0.5 (.5)	0 (0)	2.5	10	25%
Focus on past success	4	2.5 (.63)	3	4 (1)	3 (.75)	2 (.5)	3 (.75)	3.5 (.88)	3 (.75)	2.5 (.63)	3.5 (.88)	30	40	75%
Overall fidelity score		2.13	2.1	4.52	6.82	4.07	5.52	1.72	5.64	3.56	4.09			
Fidelity score in %		21.3%	21%	45.2%	68.2%	40.7%	55.2%	17.2%	56.4%	35.6%	40.9%			

*List of BCTs coded in the DAFNE manuals for session 18, number of times each BCT was delivered in each observation (fidelity score per BCT), number of times each BCT was expected to be delivered across 10 observations for 100% fidelity, and fidelity of delivery score across 10 observations in %

Table 2.

Fidelity scores for session 21 (goal-setting and action planning session), calculated per BCT and per observation

Session 21	**Number of times BCT was coding in the manual**	**Total no. of times BCT was delivered per observation (calculated fidelity score per BCT)**											**Total number of times BCT expected to be delivered for 100% fidelity**	**Overall fidelity score per BCT in %**
		obs1	**obs2**	**obs3**	**obs4**	**obs5**	**obs6**	**obs7**	**obs8**	**Obs 9**	**Obs 10**	**Total**		
Problem solving	2	2 (1)	2 (1)	2 (1)	2 (1)	2 (1)	2 (1)	2 (1)	2 (1)	2 (1)	2 (1)	18	20	90%
Goal setting (outcome)	3	3 (1)	2.5 (.83)	3 (1)	2 (.66)	3 (1)	2 (.66)	3 (1)	3 (1)	3 (1)	2 (.66)	26.5	30	88%
Action planning	5	5 (1)	5 (1)	5 (1)	5 (1)	5 (1)	5 (1)	5 (1)	5 (1)	5 (1)	5 (1)	50	50	100%
Social support (unspecified)	1	1 (1)	1(1)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	10	10	100%
Social support (practical)	1	0 (0)	0.5(0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)	2.5	10	25%
Instruction on how to perform the behaviour	1	1 (1)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	0.5 (.5)	1 (1)	0 (0)	4.5	10	45%
Demonstration of the behaviour	1	1 (1)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	0.5 (.5)	1 (1)	0 (0)	4.5	10	45%
Behavioural practice/ rehearsal	1	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	10	10	100%
Overall fidelity score		7	.67	.625	.833	0.875	.583	.625	.875	.875	.707			
Fidelity score in %		87.5%	67%	62.5%	83.3%	87.5%	58.3%	62.5	87.5%	87.5%	70.7%			

* List of BCTs coded in the DAFNE manuals for session 21, number of times each BCT was delivered in each observation (fidelity score per BCT), number of times each BCT was expected to be delivered across 10 observation s for 100% fidelity, and fidelity of delivery score across 10 observations in %.

8.10 Appendix X: Centre invitation letter Study 3

Goal-setting in DAFNE, educators perspectives

Invitation Letter

Thank you very much for taking part in our previous observational study focusing on DAFNE's goal-setting component. While this study is still ongoing, we are starting a small follow-up study in this subject that we would like to invite you to participate in.

This research is part of a funded PhD by the Health Research Board (HRB) and is being led by Milou Fredrix, PhD Candidate within the Health Behaviour Change Research Group (HBCRG) at the School of Psychology in NUI Galway, in co-operation with Dr. Molly Byrne, Director of the HBCRG, Dr. Jenny McSharry, Assistant Director of the HBCRG and Dr. Sean Dinneen, Head of School of Medicine, NUI Galway. This study has been approved by the Central DAFNE Office UK and has gained ethical approval from the Galway Hospital Ethics Board.

This study is a qualitative study aiming to explore DAFNE educators' perspectives on the value and the effectiveness of the goal setting component of DAFNE and would entail one-off interviews with 2-3 DAFNE educators active in your clinic.

Thank you for taking the time to read about our study, and we look forward to your response.

Best wishes,

Milou Fredrix (PhD Candidate)
Health Behaviour Change Research Group
G042 AMBE | School of Psychology
National University of Ireland, Galway

NUI Galway
OÉ Gaillimh

HEALTH BEHAVIOUR CHANGE
RESEARCH GROUP

Why is this study being conducted?

The DAFNE programme has become part of routine diabetes care in Ireland. Unfortunately, research shows that DAFNE sometimes fails to help participants instil key self-management practices into their lives on a long term basis. A core component of DAFNE is goal-setting. Goal-setting techniques can effectively change behaviours if done properly. However, little is known about how educators experience the delivery and operationalisation of this component in practice.

Who is conducting this study?

The principal investigator for this study is Milou Fredrix, PhD Candidate within the Health Behaviour Change Research Group (HBCRG) at School of Psychology in NUI Galway. This research is part of a PhD project funded by the Health Research Board (HRB) and being conducted in co-operation with Dr. Molly Byrne, Director of the HBCRG, Dr. Jenny McSharry, Assistant Director of the HBCRG and Dr. Sean Dinneen, Head of School of Medicine, National University of Ireland, Galway.

Why have I been contacted?

You have been selected based on your previous participation in this series of research.

What does participation in this study mean for my centre?

This study would involve one researcher (Milou Fredrix) coming into the diabetes clinic and conducting 30 minutes one-to-one interviews with the different DAFNE educators working in the clinic. The educators will be asked a series of questions centered around exploring their perspectives on the value and effectiveness of the goal setting component of DAFNE. The interview will be audio recorded and transcribed.

Will the privacy of staff and patients be protected?

Yes! Educators will be given information and asked to give informed consent for the interviews and audio recordings. In addition to this, in any report or publication of the study findings, individual centres or their staff will not be identified. All information provided as part of the study will be treated as confidential and recordings will be anonymised.

What if I would like more information?

You can contact the researcher or the researcher's supervisor to request more information using the following details:

Principal investigator: Milou Fredrix G042 AMBE | School of Psychology National University of Ireland, Galway E: m.fredrix1@nuigalway.ie T: +353 85 834769	Research Supervisor: Dr. Molly Byrne 1043 AMBE | School of Psychology National University of Ireland, Galway E: molly.byrne@nuigalway.ie T: + 353 91 495182

8.11 Appendix XI: Consent form and information letter Study 3

ELM PARK,
DUBLIN 4
Department of Endocrinology & Diabetes Mellitus

PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE:

Goal-setting with T1DM patients: qualitative study examining educators views on the goal-setting component of DAFNE

NAME OF PRINCIPAL INVESTIGATOR: Milou Fredrix

You are being invited to participate in a research study. Thank you for taking time to read this.

WHAT IS THE PURPOSE OF THIS STUDY?

The goal-setting component of DAFNE is quite different from the other components of the course. This research study aims to find out more about how DAFNE educators feel about delivering the goal-setting sessions. Furthermore, we are interested to get educators' perspectives on the value and effects of these sessions.

WHY HAVE I BEEN CHOSEN?

You have been chosen based on your function as a DAFNE educator.

WHAT WILL HAPPEN IF I VOLUNTEER?

If you agree to participate in this study, an interview will take place with the researcher. Ideally, the interview will take place within your diabetes

centre/hospital in a private setting; however the interview can be phone based as well. This interview will take around 20-30 minutes and will be focused around discussing your views on the goal-setting component of DAFNE. The interview will be audio-recorded. The content of this audio-recording will be transcribed.

ARE THERE ANY BENEFITS FROM MY PARTICIPATION?

You will not benefit directly from taking part in this study but the information we will obtain may provide further knowledge of the workings of DAFNE.

ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?

The anticipated risks for this study are limited. You are free to skip any question within the interview, if you feel any kind of discomfort. Other anticipated risks within this study exist around data confidentiality. However, to avoid the risk of someone accessing the audio-files, audio recordings will be safely secured on password protected computer files, and any devises used in this study will be encrypted.

WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?

Nothing, your participation in this study is completely voluntary. If you do not want to take part in this study, you simply do not sign the consent form on page 3. Please remember that, even if you agree to take part in this study, you can withdraw from this study at any time without any consequences. You don't have to provide a reason to withdraw.

CONFIDENTIALITY

The interview will be audio-recorded. The content of this audio-recording will be transcribed. While the original recording could possibly identify you, names and hospital names will be replaced by participant numbers and aliases during

data transcription, meaning that information cannot be traced back to you. The original recording and any written material will be stored safely within the University of Galway and will only be accessible by the research team for 5 years. The audio-recording will be used for the purpose of this research only. You or the hospital will not be personally identified in this research.

COMPENSATION

No paid compensation will be given for participation in this study.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?

This study is organised by Milou Fredrix, PhD student at the National University of Galway, and funded by the Health Research Board Ireland.

HAS THIS STUDY BEEN REVIEWED BY AN ETHICS COMMITTEE?

The Chairperson of the Ethics committee of St. Vincent's Healthcare Group, has reviewed and approved this study.

CONTACT DETAILS

For further information about this study, please contact:

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RESEARCH PARTICIPANT'S RIGHTS

If you have any questions about your rights as a research participant, then you may contact the Hospital's Quality & Patient Safety Department 01 2214013

PLEASE TICK YOUR RESPONSE IN THE APPROPRIATE BOX

- I have read and understood the Participant Information YES ☐ NO☐
- I have had the opportunity to ask questions and discuss the study YES ☐ NO ☐
- I have received satisfactory answers to all my questions YES ☐ NO ☐
- I have received enough information about this study YES ☐ NO ☐
- I understand that I am free to withdraw from the study at any time without giving a reason and without this affecting my future medical care YES ☐ NO ☐
- I agree to take part in the study YES ☐ NO ☐

Participant's Signature: _____ Date: _____

Participant's Name in print: _____

Gender: _____

Age: _____

Investigator's Signature: _____ Date: _____

Investigator's Name in print: ____Milou Fredrix_____

8.12 Appendix XII: The COREQ checklist Study 3

Item	Description
Domain 1: Research team and reflexivity	
Personal Characteristics	
1. Inter viewer/facilitator	One author (MF) conducted the interviews
2. Credentials	BSc. in Psychology and Neuroscience, MSc. in Health and Social Psychology.
3. Occupation	PhD Candidate in the Area of Psychology and Health
4. Gender	Female
5. Experience and training	MF has been trained in qualitative methods and design and has experience in conducting focus groups
Relationship with participants	
6. Relationship established	At the time of the interview, MF had collaborated with the educators on one previous study and had contacted participants via email or telephone to discuss arrangements for interviews. Therefore the educators were familiar with the researcher who conducted the interviews.
7. Participant knowledge of the interviewer	Participants were aware that the researcher was conducting a PhD in the area of Goal-setting in DAFNE.
8. Interviewer characteristics	The researcher has a background in Health Psychology. The researcher was closely engaged in the research process and therefore unable to avoid personal bias.
Domain 2: study design	
Theoretical framework	
9. Methodological orientation and Theory	Qualitative research guidelines by Braun and Clarke (2013) advice that interviews are the most frequently used strategy for ‘exploring, understanding and perception’ categories of research questions. Given the objectives of this research, interviews were thus

	suitable. Additionally, interviews tend to generate rich and detailed data about individual experiences (Braun & Clarke, 2013), which is vital in a relatively understudied area as providers' perspectives on goal-setting in DSME. Thematic analysis was used in this study. An inductive approach was adopted. This research took a critical realist ontological approach, as we assume that reality cannot be separated completely from human practices and is socially influenced and context dependent. However we still assume that a separate reality can be partially accessed in research and that results from this research should be approached as authentic and reliable (Braun & Clarke, 2006). A contextualism epistemological assumption is underpinning study 3, as we feel that knowledge will always be perspectival and will somewhat emerge from context. However, we believe that while a single truth is difficult to reveal through research, knowledge gained from this research will be true in a certain context and therefore vital to creating a knowledge base.
Participant selection	
10. Sampling	Due to the nature of the research and the fact that there are only a limited number of DAFNE educators active throughout the republic of Ireland, a convenience

	sampling strategy was utilized within this study. Based on examples from previous work (2), the sample size this study aimed for was 10 educators. All educators operational in 4 different diabetes centres were approached (n=11). The centres were selected based on their geographic location and the number of expected DAFNE courses per year. Educators were selected based on their credentials as a DAFNE educator, the centre they were active in, and on their willingness and availability to participate in the study. DAFNE educators who had delivered at least one DAFNE course in the last year were eligible.
11. Method of approach	Educators were contacted by the lead researcher via email and asked to participate. Educators were given a full information letter describing the details of the study at the time of approaching to enable informed decision making. While most educators expressed a willingness to participate in the study. A number of educators were not as responsive to in subsequent email contact to set up an interview time. This was due to self-reported professional time-constraints. The delayed responses and the hospital ethics procedure were the main causes for the relatively long duration period of the study.
12. Sample size	There were 10 participants in the study.
13. Non-participation	1 educator did not respond to an email invitation. All participants who agreed on a date and a time took part in an interview.
Setting	
14. Setting of data collection	Data was collected at the diabetes clinics and hospitals where the educators were based. 2 interviews took place

	via telephone due to geographical location and availability of the educators.
15. Presence of non-participants	No non-participants were present at the interviews.
16. Description of sample	Characteristics of the sample can be seen in Table 1.
Data collection	
17. Interview guide	The topic guide used for the interviews was developed following examples from other qualitative research (Morrissey et al., 2018) in the area and incorporated theory based questions. The topic guide was reviewed by a member of the research team with significant qualitative research experience, before piloting the guide on one participant. The data from the pilot interview was from a legitimate participant to judge the interview guide for suitability. The interview guide was considered suitable, and fundamentally the same guide was used in subsequent data collection. However, to be responsive to the data, an iterative approach was used (22). This meant that a small number of questions were added as new ideas emerged from early data collection and exploration. The final topic guide can be found in Appendix A.
18. Repeat interviews	No repeat interviews were carried out.
19. Audio/visual recording	An audio recording was made during the interviews using a discrete reordering device.
20. Field notes	Field notes were made during and after the interviews by the interviewer.
21. Duration	The interviews averaged 31 minutes (range 21-39)
22. Data saturation	Transcripts were reviewed after each interview, and full thematic analysis was conducted with data from 8 interviews. Two additional interviews were conducted and analysed for further themes. Data saturation was

	reached after participant 8 as no new themes were identified in the final 2 interviews (2)
23. Transcripts returned	Transcripts were not returned to participants for comment and/or correction.
Domain 3: analysis and findings	
Data analysis	
24. Number of data coders	One researcher (MF) coded the data. The coding was reviewed by a member of the research team with significant qualitative research experience at each stage of the analysis (JMS). A randomly selected 20% of the original transcripts were checked against the identified themes by MF and JMS, to aid discussion and refinement, and to check whether themes represented the transcripts accurately.
25. Description of the coding tree	Open coding or data derived coding was firstly performed. This consisted of transcripts being read thoroughly and sections of text being assigned to descriptive codes that reflected the semantic content of the data. Content of following transcripts was constantly compared to codes that were already established. After forming the codes, they were grouped into categories, which were then grouped into themes.
26. Derivation of themes	One researcher (MF) developed the themes. The emerging themes were reviewed by a member of the research team with significant qualitative research experience (JMS). Themes were visualised in a potential 'thematic map' leading to the development of the final 5 broader overarching themes
27. Software	Data was managed using NVivo 11.
28. Participant checking	Participants did not provide feedback on the findings.
Reporting	

29. Quotations presented	Participant quotations are presented to illustrate the themes/findings. Each quotation is identified using a participants' number which is labelled as 'Educator' (E) and number (X).
30. Data and findings consistent	In line with TA guidelines, data pattern frequency, as well as level of meaning for answering the research questions, was taken into account in theme development. Therefore, the unit of analyses was the theme rather than the prevalence of statements. However, there is high consistency between the data presented and the findings. While we include some statements of quantification such as 'some' or 'several', these do not always aim to provide estimates of prevalence.
31. Clarity of major themes	All major themes are clearly presented in the findings.
32. Clarity of minor themes	There is a description of sub themes in the findings.

8.13 Appendix XIII: Topic Guide Study 3

Final Topic Guide including prompts used in study 3

Briefing:

1) Thank participant for agreeing to take part.
2) Introduce self.
3) As described in the Participant Information Sheet we are interested in educator's views on the goal-setting part of the DAFNE programme.
4) If at any time you do not wish to answer a question that is perfectly fine.
5) I would like to record our conversation. The recording will be typed out, but everything you say will be anonymous. Your name and any names or places you mention will be taken out at data transcription, so that if someone reads your interview they would not know who you are.
6) If, at any stage, you wish to stop the audio recorder, please let me know.
7) Do you have any questions?

Introduction/ warm up questions:

1. How long have you been a DAFNE educator?
2. What is your professional background (Dietician, nurse)?
3. How do you feel about teaching DAFNE?

We will be mostly focusing on the goal-setting part of DAFNE in this interview. You are the expert and I am very interested in your honest opinions about this part. The more you can tell me, the more I will learn about this.

Quality assessment of the goal-setting and action-planning sessions.

1. Have you ever delivered or witnessed the goal-setting and action planning part of DAFNE? How recent?
2. Could you briefly describe this part of the DAFNE course?
    a. What happens, how long?
3. How do you feel about the goal-setting and action planning component of DAFNE?
    a. How useful/beneficial do you feel these sessions are to DSME? Why?
    b. What parts most useful?

   c. What parts less useful?
4. How do you think other educators feel about these type of components?
5. Do you feel sufficient time is spend on this component?
6. How do you feel it fits in with the rest of the DAFNE curriculum?
7. How do you feel the group responds to this part of the programme?
   a. Positive/ negative? Example?
8. Could anything be improved about these sessions?
   a. Elements missing that participants might benefit from?
   b. Feedback from participants that would make you think of possible improvements?

Assessment of delivery experience (only applicable if educator has delivered goal-setting session)

1. How do you feel when delivering these sessions?
   a. Confident/ unsure? Do you enjoy delivering this particular part more or less? Why?
2. How do you think other educators feel when they are delivering these sessions?
   a. Confident/ unsure? Enjoy delivering this particular part more or less? Why?
3. Are there any things you struggle with when delivering these particular sessions?
   a. Particular elements
      - less comfortable with when delivering?
      - very comfortable with when delivering them?
4. Do you ever struggle with delivering these sessions according to the educator's manual?
   a. Reasons for struggle?
   b. See any value in deviating from manual?
      - Experiences of the week? Example?
5. Do you remember, when you were trained to be a DSME educator, what did they say about goal setting?

   a. Special instructions on how to deliver?
   b. Would there have been something more valuable in training for this piece? Anything missing, anything added?

Assessment of delivery experience (if educator has NOT delivered goal-setting session personally)

1. How do you think other educators feel when delivering these session?
   a. Prompts: confident/ unsure
      i. Particular elements
      ii. less comfortable with when delivering?
      iii. very comfortable with when delivering them?
   b. How would you feel about delivering this part of the course?
2. When you were trained to be a DSME educator, what did they say about goal setting?
   a. Special instructions on how to deliver?
   b. Would there have been something more valuable in training for this piece?
3. When you are delivering DAFNE sessions, do you ever struggle with delivering the session according to the manual?
   a. Possible reasons for struggle?
      - See any value in deviating from manual? Experiences of the week? Example?

Assessment of programme receipt

1. To what degree do you feel participants understand the content of the session?
   a. How well do they know what to do? Example?
   b. Do they generally set goals that are in line with the instructions (in terms of behaviour as opposed to outcomes; specific and small)?

Assessment of programme enactment

1. From your experience, to what degree do you feel patients use the set goals and the action plan after the DAFNE programme?
   a. Do you feel participants look at these goals again after DAFNE

b. Do educators ever look at the goals/ action plans again?
    i. To what degree do you feel this should happen?

2. From your experience, what are the barriers that people experience when pursuing their goals after DAFNE? (could you give example)
3. From your experience, to what degree do you feel patients achieve the goals they set after DAFNE? (could you give example)
4. From your experience, could there be improvements to DAFNE that would help patients achieve their goals more?

Closing:

Before we end the interview, is there anything else that you would like to share that I haven't asked yet?

I want to thank you for sharing your views.

8.14 Appendix XIV: Article-based PhDs, Guidelines for the College of Arts, Social Sciences, and Celtic Studies

General comment

The standard of scholarly achievement and professionalism expected of an article-based PhD is identical to that expected of the traditional monograph-type thesis. An article-based PhD will be no less rigorous academically than a monograph and should still not exceed 80,000 words as per university norms. Reference also section 6.2.6 'Article-based' PhD in the university guidelines for research degree programmes.

Relevance to disciplines within College

It is recognised that article-based PhDs are not equally relevant to all disciplines within the College. Certain disciplines or sub-disciplines (for example Physical Geography, Archaeology, Psychology, Social Work and Education) are more likely to encounter greater take-up of this format among their doctoral students. The traditional monograph route is the preferred option in Humanities, Languages, Literatures & Cultures and in many sub-disciplines of Sociology & Political Science and of Geography and Archaeology. There is no obligation on any discipline within the College to promote the article-based format over the traditional monograph format. The decision of a student to avail of this format should be made early in the PhD in accordance with the norms of the discipline and with the agreement of the supervisor(s) and GRC.

The number and status of publications

A minimum number of substantial articles, based on the disciplinary norm, should make up the core of an article-based PhD thesis:

- In Geography, a minimum of three articles should make up the core, where the PhD candidate is the primary author.
- In Archaeology, a minimum of three articles should make up the core, where the PhD student is the single author.
- In both Geography and Archaeology, two of the articles should have been

accepted for publication by internationally peer-reviewed journals relevant to the discipline in question, with the third submitted for review.

- **In Psychology, three articles should make up the core of the PhD, with 2 of these accepted for publication and the third submitted for review.**
- In Education, a minimum of two accepted substantial single-authored articles are required.
- In Political Science and Sociology, a minimum of three accepted articles are required.

Further articles may also be submitted. In the case of jointly-authored articles (for instance, in Geography), the applicant should be the primary author and must be capable of demonstrating that he/she made a substantial contribution to them. These articles should have either been published or have been accepted for publication by highly-ranked peer-reviewed journals relevant to the discipline in question. In the case of material accepted for publication, the student's supervisor/GRC must be able to verify that the manuscript has passed all stages of the peer review process.

The PhD thesis containing these articles should make a coherent and substantial contribution to knowledge in a specific field in order to qualify for award of the PhD degree.

In the case of jointly-authored papers, the candidate's contribution to the authorship and content of the papers must be made explicit in the other required material for PhD thesis.

It is the responsibility of the supervisor and GRC to sign-off that the candidate's work is worthy of PhD thesis for examination (EOG-020 Approval for Examination form). In other words, the supervisor and GRC should have reached a judgement that, in their view, the student's work is of the standard to merit the award of a PhD. During the *viva*, close attention should be paid to the nature and quality of the articles, and in the case of jointly-authored material, to the student's role in it. It

must be emphasised that the examiners retain final judgment on the quality of the thesis.

Required material

In addition to the articles, the PhD thesis must include the following, subject to disciplinary norms:

- a thorough critical review of previous scholarship and literature on the topic;
- a chapter locating the candidate's work within the existing scholarship, which will explicitly articulate the key research question(s) addressed by the candidate and the chosen methodology/theoretical framework, as appropriate;
- a concluding chapter, which draws the substantive material in the articles together so as to demonstrate their coherence and the full extent of their contribution to knowledge;
- in the case of jointly-authored papers (for instance, in Geography), the candidate's contribution to the authorship and content must be made explicit in this section;
- a full bibliography.

Supporting or supplementary material:

As appropriate to the discipline, the PhD thesis may be supported by appendices consisting of, but not limited to, the following kinds of information:

- Databases of key evidence
- Lists and examples of archival material consulted
- Research questionnaires, such as those used in the Social Sciences
- Statistical analyses of full data-sets

Such detail is often inappropriate in the context of a journal, where word-counts are at a premium, but are essential in the context of a PhD thesis for a PhD.