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Using mobile phones to collect patient data: Lessons learned from the SIMPle Study.

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ORIGINAL PAPER

ABSTRACT

BACKGROUND

Mobile telephones offer new opportunities to collect real time data from patients with acute illnesses such as urinary tract infections (UTI) in a much more efficient and interactive way. Benefits of using mobile data collection methods include automated data upload without data loss which can be an issue when using other data collection methods such as paper based surveys. This feasibility study explores differences in collecting data from patients with UTI using text messaging, smartphone app (UTI diary) and online survey. It also discusses lessons learned from integrating mobile data collection into a randomised control trial.

METHODS

Participants included UTI patients consulting in a general practice that was participating the in SIMPle (Supporting the Improvement and Management of UTI) intervention. SIMPle was designed to improve antimicrobial prescribing for UTI in the community. Patients were invited to reply to questions regarding their UTI either via a prospective text message survey or smartphone app (UTI diary); or retrospective online survey. Data was collected from 371 patients who replied to the text message survey, 71 UTI patients through the smartphone symptom Diary' app (UTI Diary) and 91 online survey participants.

RESULTS

The age profile of UTI Diary app users was younger than that of the text message and online survey users. The largest dropout for both the text message survey respondents and UTI Diary App users was after the initial opt-in message, once the participant completed question 1 or Day 2 they were more likely to respond to the remaining questions/ days.

CONCLUSIONS

This feasibility study highlights the potential of using mobile data collection methods to capture patient data. As well as improving the efficiency of data collection, these novel approaches highlight the advantage of collecting data in real time across multiple time points. There was little variation in number of patients responding between text message survey, UTI Diary and online survey but, more patients participated in the text message survey then the UTI Diary App. A Researchers choice between designing a text message survey or UTI Diary App will depend on age profile of patients and the type of information they desire.

TRIAL REGISTRATION: The SIMPle intervention is registered with ClinicalTrials.gov on 26th July 2013, ID number NCT01913860.

KEY WORDS

Smartphone Applications, Mobile survey, Antimicrobial resistance, primary care, quantitative, prescribing, Urinary Tract Infection

BACKGROUND

Paper-based surveys have been the standard for collecting patient data in health research. This data collection method is limited due to issues related to data entry and storage costs. Mobile phones offer new opportunities to collect real time data in a much more efficient and interactive way including automated data upload without data loss which can be an issue when using other data collection methods [1]. Mobile phones have already been used successfully in the past in the development of health and behavioural change interventions. Examples include in the areas of diabetes self-management, weight loss, physical activity, smoking cessation, and medication adherence [2].

Text messaging or Short Messaging System (SMS) have become a ubiquitous method of communication displacing more traditional landline infrastructures [3]. In 2009, Irish citizens were the second highest users of SMS in Europe, sending an average of 2,700 text messages per year [4]. In 2010, there were an estimated 5.5 million mobile telephone subscriptions in Ireland equating to a mobile telephone penetration of 119% [5]. Text messaging is fast and convenient giving users flexibility to respond at any time or place while presenting new opportunities to evaluate health related interventions. The use of automated text messaging services for evaluating health interventions is growing.

According to a recent survey, 75% of people in Ireland are smartphone users[6]. In 2009, worldwide mobile app downloads amounted to approximately 2.52 billion and are expected to reach 268.69 billion in 2017 [7]. Smartphones offer researchers new data collection opportunities due to the way in which they are used and how data is shared. Smartphone apps can reduce data management and processing time for researchers, however technical difficulties are considered a disadvantage [8]. Smartphones have been used in the self-management of health, adaptive learning, sharing platforms and social support is offered to

the individual [9]. However, only recently have apps been used to capture data related to health for the purposes of scientific research. The first initiative in this direction has recently been launched by Apple, who introduce a mobile platform for biomedical research to boost large-scale health studies [10]. Mobile applications are transforming how medicine is conducted and taught in the health care setting [11], however, there is little evidence of how they can be used to rigorously monitor patient outcomes. To our knowledge no study has captured real-time data from patients to record UTI symptoms and treatment using a smartphone app.

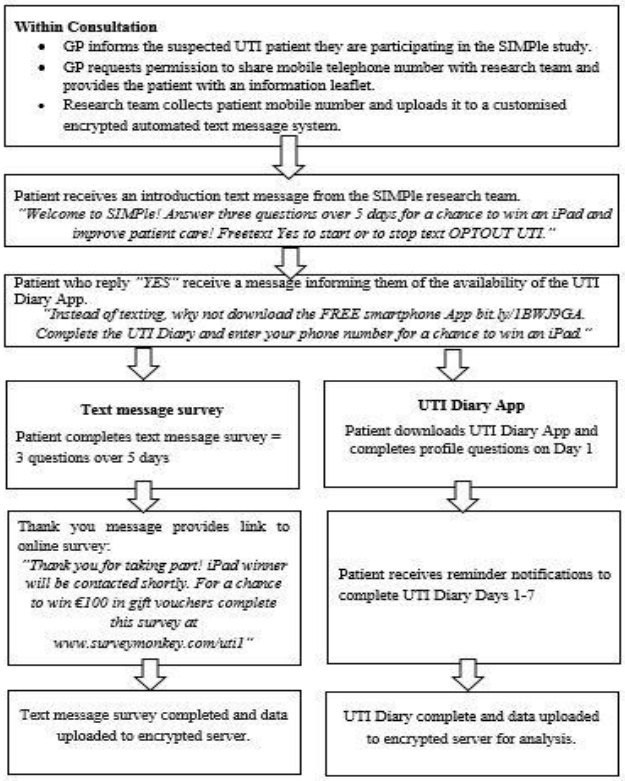
To our knowledge this is the first time SMS text messaging and smartphone apps have been used as part of an evaluation of a complex intervention. This paper explores the feasibility of using novel mobile data collection methods to enhance evaluation of complex interventions. This paper illustrates how patient data was collected via a text messaging survey, smartphone symptom diary app and retrospective online questionnaire within the SIMPle study. It concludes by discussing the lessons learned from adopting these novel approaches and the potential implications

METHODS

Procedure

Data was collected from Urinary Tract Infection (UTI) patients through text message survey, smartphone Symptom diary app (UTI Diary) and online survey. Urinary Tract Infections (UTI) are the second most common infection presenting in primary care. UTI symptoms include feeling unwell, frequency and urgency or urination, pain when passing urine and pain in the lower abdomen [12, 13]. GPs within 30 practices participating in the SIMPle study [14] were asked to invite patients with suspected UTI to provide their mobile phone number to the research team. Figure 1 summarises how the data was collected.

Figure 1: Data Collection Procedures



The research team initiated contact with UTI patients via text message. The first text message confirmed consent before further participation. Patients who replied YES (indicating consent) were invited to complete a text message survey or download the UTI diary app. Patients who completed the text message survey were sent a link to an online survey once they had responded to three questions over five days.

Text Message Survey

The text message survey was designed to capture data from patients on the type of treatment, when they started antibiotic treatment (if at all) and the duration of symptoms. The text message workflow was designed using a customised process which included a 24 hour delay between each question. Text messages were sent at noon each day. Each question used a different keyword (Yes, UTI, START, DAY and OPTOUT UTI). These keywords were used

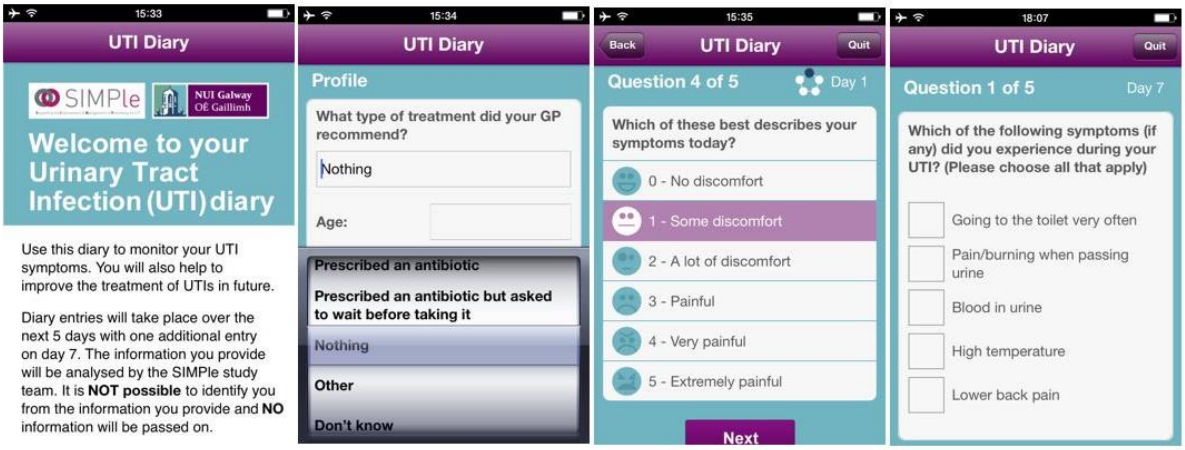
to differentiate responses to each of the questions. Questions were limited to 160 characters including spaces, keywords, response options and opt out instructions. An example of one of the questions was: *"Did the GP give you a) Antibiotic prescription b) antibiotic prescription & asked to wait 2days c) other. Freetext UTI & the answer (eg UTI a) or OPTOUT UTI"*. All messages were free to send and receive and patients could opt out of the process at any stage. Text messages were pre-tested for comprehension.

UTI Diary App

The UTI diary app and online survey focused on examining the type of symptoms, severity of symptoms and treatment recommended. Questions were developed from previous international qualitative and quantitative studies and further expert opinion. Both the UTI Diary app and online survey were pretested to ensure face validity of measures and usability.

The UTI diary app captured data in 'real time' over 7 days (day 1-5 and day 7) (Figure 2). The UTI diary app was compatible with Android and IoS (Apple) platforms. Upon downloading the UTI diary app (Day 1), participants completed profile questions (age, gender, employment status), general health, severity of symptoms and outlined the type of treatment the GP recommended. On days 2-5, the same 2 questions were repeated; severity of symptoms and medication taken (if any). On day 7 participants were asked the same questions as day 2-5 with 3 additional questions on symptoms, satisfaction of information provided within the GP consultation and general health status. UTI Diary app participants received daily reminders to complete their diary entry.

Figure 2: Screen grabs from the UTI Diary App



Online Survey

The online survey was completed approximately 5 days after the UTI consultation via surveymonkey. The online survey was much longer than the UTI diary and included 23 questions on patient satisfaction with the consultation, type and severity of symptoms, treatment and demographics. The online survey included more extensive scales on for example patient satisfaction and patient demographics.

Participants and Sample

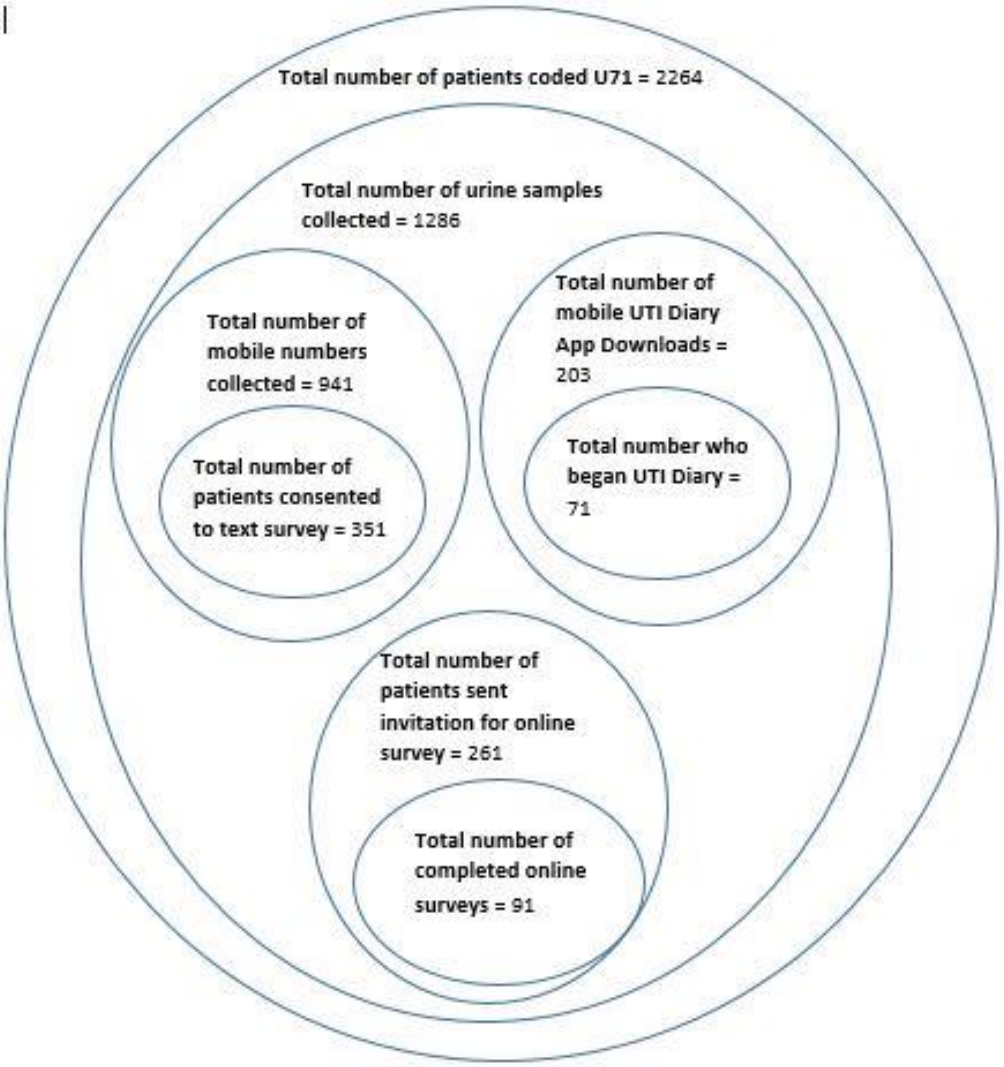
During the SIMPle intervention period (9 months), 2264 patients were coded U71 in the GP patient management software meaning these patients were identified as patients with UTIs [15]. GPs were asked to submit a urine sample to the laboratory for all patients who they coded as U71, patient mobile telephone numbers were written on the urine sample form and collected by the researchers. During the intervention period a urine sample was obtained and sent to the laboratory from 1286 patients or approximately 50% of index consultations. 941 mobile telephone numbers were collected from these urine sample forms and these patients

were sent an invitation text message to participate in the text message survey. 351 (37%) patients responded to the initial invitation to participate in the text message survey. The UTI diary app was downloaded 203 times (175 iOS users and 28 Android users) over a 6 month period. Of patients who downloaded the UTI diary app, 71 (35%) responded of whom 31 completed the 7 days of the UTI diary app. Of the 261 who completed the text message survey, 91 (35%) responded to the online survey.

Data Management and Analysis

Data from the text message survey and UTI Diary App was remotely uploaded and transferred to a secure password encrypted database. Online survey data was downloaded from the Survey monkey database. Missing data was coded prior to analysis. The text message survey, UTI Diary app and online survey were analysed separately. The data was analysed to describe subjects' demographic characteristics and symptoms and severity experienced. All responders' answers were automatically entered into a data file which was checked for accuracy by two independent researchers.

Figure 3 Summary of sampling frame



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187 Data are presented as frequencies and univariate analysis was performed using χ^2 tests (at
188 $P \leq 0.05$, 95% Confidence Interval) to identify variables associated with antimicrobial
189 prescribing amongst UTI diary app users only. To evaluate if antimicrobials improved the
190 speed of recovery, a variable was created to indicate the day at which they were considered
191 improved (which was set at level 2 or below on the pain scale and a second analysis was
192 performed with level 3 or below). Based on this outcome, a Cox Proportional hazards model
193 with antimicrobial prescription as an independent predictor was calculated. Data was
194 analysed using SPSS (version 21.0).

195 **RESULTS**

Demographic Characteristics

Demographic characteristics of text message survey, UTI Diary App, and online survey participants are provided in Table 1.

Table 1: Demographic characteristics of participants

Characteristics		**Text Message Survey** (N=351)		**UTI Diary App (N=71)**		**Online survey (N=91)**	
		N	**%**	**N**	**%**	**N**	**%**
Age (years)	18-24	29	9	30	42	13	14
	25-34	65	20	18	25	23	25
	35-44	63	19	13	18	28	31
	45-54	64	20	6	9	13	14
	>55	107	33	4	6	14	15
Gender	Male	22	6	12	17	4	4
	Female	326	94	59	83	87	96
Employment	Employed	-	-	50	70	65	71
	Unemployed	-	-	10	14	15	17
	Students	-	-	11	16	11	12
Antimicrobials prescribed	Yes	132	73	51	72	86	95
	No	18	10	20	28	5	5

Across the three data collection tools, participants were mostly female. The majority of UTI Diary app participants were aged between 18 and 34 (67%), which is the number completing the text message survey (29%) and online participants (39%) in this age group. The over 35 year age group represented 33% in UTI diary app group, 72% of the text message group and 60% of the online survey.

The majority of participants received an antimicrobial prescription and this was similar in the UTI diary app group (72%) and text messaging group (73%) but much higher in the online survey group (95%).

Text Message Survey Response

The time taken to respond to the text survey varied between participants. For the opt-in message and question 1, more than half of patients responded in less than 1 hour, while a further 30% took more than 12 hours to respond. For questions 2 and 3, nearly all participants responded within less than an hour (Q2 97.5%, Q3 99.5%).

Table 2 summarises the number of times each message was sent before response. The largest dropout from respondents was after the initial opt-in message, once the participant completed question 1 they were more likely to respond to the remaining questions.

Table 2 Number of times the text message questions sent to UTI patients

Number of times message sent	**Opt in Message** (N=351)		**Question 1** (N=270)		**Question 2** (N=268)		**Question 3** (N=263)		**Thank you message** (N=261)	
	N	%	n	%	n	%	n	%	N	%
1	251	71.5	154	57.0	161	60.1	190	72.2	261	100.0
2	99	28.2	116	43.0	100	37.3	73	27.8		
3	1	.3			4	1.5				

4		2	.7
5		1	.4

The majority of participants who choose to opt out (22.8%) did so at the beginning of the process. For question 1, 2 and 3, 25% did not respond.

Participants regularly used incorrect keywords; for example UTI instead of the question 2 keyword ‘start’. When wrong key words were used, responses were removed from analysis.

UTI Diary App

Unlike the text message survey, there was no pattern as to when people completed the UTI diary. The patient’s response time depended on when they downloaded the UTI Diary App.

Table 3 summarises the overall responses for the UTI diary App. Similarly to the text message survey there was a drop off between Opting in on Day 1 and Day 2- Day 7. However, Table 3 highlights that once participants completed Day 2 they were less likely to drop out of participating in the UTI Diary App. Finally, table 3 also highlights that UTI Diary participants did not skip any questions when completing the UTI Diary App therefore all fields provided the researchers with data.

234 Table 3 Overall response to every question in the UTI Diary App

		Day I (N= 71)		Day 2 (N= 71)		Day 3 (N=46)		Day 4 (N=42)		Day 5 (N=38)		Day 7 (N=33)	
ofile questio		n	%	n	%	n	%	n	%	n	%	n	%
	What type of treatment did your GP recommend?	71	100%										
	Gender	71	100%										
	Age	71	100%										
	No of children	71	100%										
	Work situations	71	100%										
D1-Q1	how good or bad your health is TODAY?	71	100%										
D1-Q2	How is your health in general?	71	100%										
D1-Q3	Overall, how satisfied were you with the treatment recommended by your GP?	71	100%										
D1-Q4	Which of these best describes your symptoms today?	71	100%										
D1-Q5	what medication have you taken today?	71	100%										
D2- Q1	Which of these best describes your symptoms today?			46	64.80%								
D2-Q2	what medication have you taken today?			46	64.80%								
D2 Both				46	64.80%								
D3-Q1	Which of these best describes your symptoms today?					42	91.30%						
D3-Q2	what medication have you taken today?					42	91.30%						
D3 both						42	91.30%						
D4-Q1	Which of these best describes your symptoms today?							38	90.50%				
D4-Q2	what medication have you taken today?							38	90.50%				
D4 both								38	90.50%				
D5-Q1	Which of these best describes your symptoms today?									33	86.80%		
D5-Q2	what medication have you taken today?									33	86.80%		
D5 both										33	86.80%		
D7-Q1	Which of the following symptoms (if any) did you experience during your UTI											31	93.90%
D7-Q2	how good or bad your health is TODAY?											31	93.90%
D7-Q3	How is your health in general?											31	93.90%
D7-Q4	Overall, how satisfied were you with the treatment recommended by your GP?											31	93.90%
D7-Q5	How good was your GP at explaining your treatment for your UTI?											31	93.90%
D7 all 5												31	93.90%

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Despite the relatively low number of responses to the UTI Diary App, the potential of this feasibility study is demonstrated in the analysis of the answers.

UTI Diary Response

Severity of Symptoms

Table 4 compares severity of symptoms reported on Day 1 through the UTI diary with the retrospective account of symptoms on day 5 from the online survey. Overall, double the online survey participants (39%) retrospectively rated their symptoms to be severe compared to 18% of participants providing real time data through the UTI diary app.

Table 4: Severity of Symptoms in real time participants (app) compared to retrospective participants (online survey)

UTI symptoms rated	**UTI Diary App (N=71)**		**Online survey (N=91)**	
	N	%	N	%
Mild	28	39	6	7
Moderate	30	42	50	55
Severe	13	18	35	39

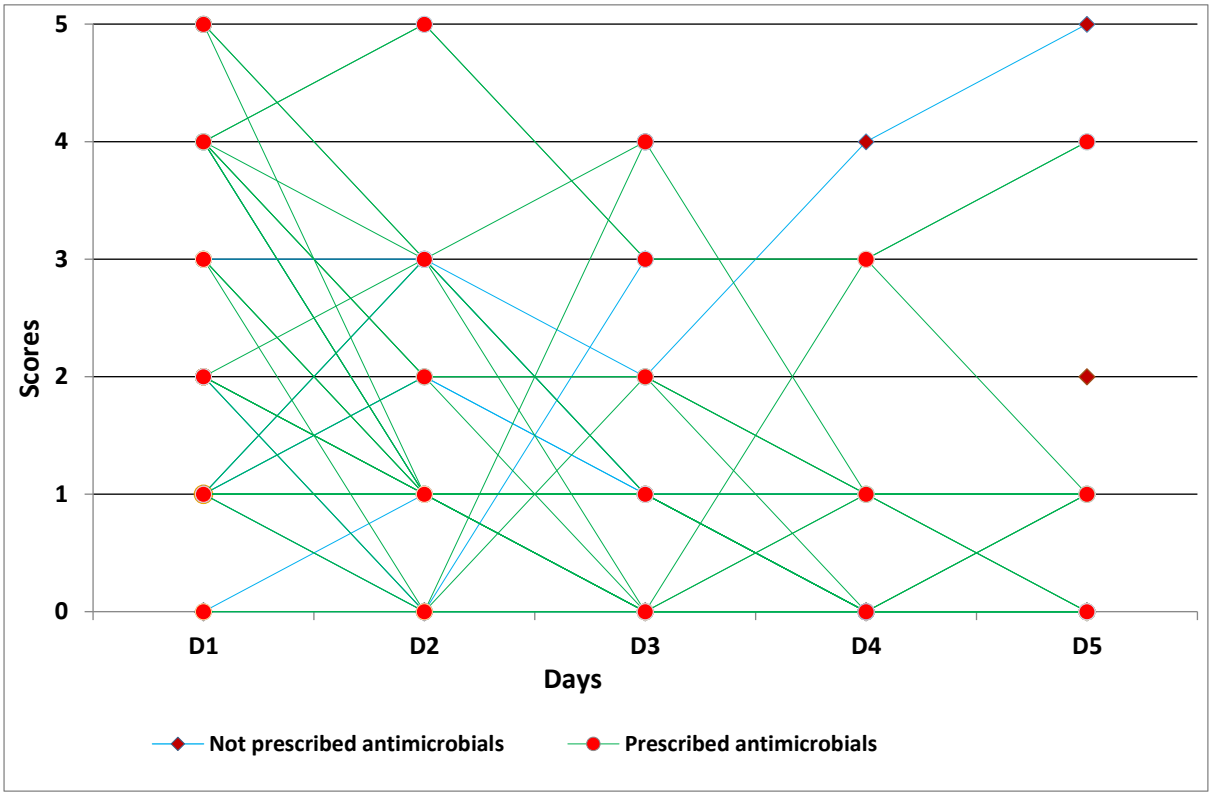
Amongst UTI Diary app participants, a significant decrease in severity was observed between day 1 and day 2 (Table 5). Of the patients who indicate worsening of symptoms between day 1 and 2, 84% started antimicrobial immediately.

Table 5: Change in the severity of symptoms of the UTI Diary app patients from day 1 to day 2

Severity of Symptoms	**No Antimicrobial prescription (N=13)**		**Antimicrobial prescription (N=33)**		**Total (N=46)**		**P-value**
	n	%	N	%	N	%	
Worse	4	31%	21	64%	25	54%	**0.023**
Same	4	31%	8	24%	12	26%	
Better	5	39%	4	12%	9	20%	

Figure 4 illustrates the severity of symptoms rated by UTI diary app users over 5 days (Day 1 to Day 5). Irrespective of antimicrobial treatment, patients improved within 1 to 2 days after their GP consultation. When comparing the speed of improvement of the patients who did and did not take an antimicrobial, no difference was observed in reaching point 2 or below on the pain scale. This was similar for reaching point 3 or below (Cox Proportional hazards not significant).

Figure 4: Severity symptoms rated by Apps user patient from day 1 to day 5 (N=71)



	Day 1					Day 2					Day 3					Day 4					Day 5				
Score	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
No Ant	7	3	4	2		4	2	3			5	1	1			2		1	1		1	1			1
Ant	14	15	8	7	4	17	3	5		1	12	3	1	2		7		2			9				1

DISCUSSION

This study shows the feasibility of collecting real-time data through novel mobile data collection methods such as text messaging and smartphone apps. These methods have the advantage of collecting data in real time across multiple time points. The respondents of this research was predominantly female which is reflective of the profile of UTI patient.

Uptake by patients

There was little variation in response between text message survey, UTI Diary and online survey but, more patients participated in the text message survey then the UTI Diary App. There may be a number of reasons for this observation. Firstly, the profile of UTI Diary app users was younger compared to text message participants. As the mean age of patients within the SIMPle study was 56.1 (standard deviation 20.7) years [15], this age group may favour text messaging over smartphone app. Secondly, the researchers were reliant on the GP to obtain patient mobile telephone numbers. Post-intervention interviews with GPs who participated in SIMPle indicated that some GPs found it difficult to explain to patients why they were requesting their mobile telephone numbers, some GPs just forgot to ask patients while others choose not to ask other patients (i.e. elderly patients) and thereby introducing selection bias. Therefore not every patient was asked to participate. Thirdly, there was also a delay of one week between the launch of the SIMPle intervention and the availability of the UTI Diary app which meant that many GPs did not receive a demonstration of the UTI Diary App. Improving the uptake of any smartphone app for use in general practice requires full collaboration from the GP, to be able to encourage download. Our study missed the buy-in of all GPs due to the delay.

The use of smartphone apps can add to improved data collection, in particular if support for both patient and GP is in place.

Text Message Design

351 patients opted in to the text message survey process which represented a response of 37%. However, as each text message needed to be 160 characters or less, the researchers were restricted in what they could ask and how questions were presented. This meant that it was difficult to ask validated questions, particularly as each text message contained opt-out instructions.

Questions were organised to follow the natural resolution of UTI and a 24 hour delay was implemented between each question in our survey to allow the resolution of symptoms before the final question. This may not have been clear to patients as some responded a few times to the same questions. An automated thank you message and better communication about the structure of the survey can improve this.

Repeating the question in the case of no response reminded patients to complete the entire series of questions. This strategy seemed to work well and if text messaging is considered, should be recommended.

Smartphone App Design

The design of the UTI Diary allowed the researcher to capture real time information on the patient and their symptoms over seven days. Unlike the text message survey, its design was not restricted by character length, however cost of design may be an issue.

Reminder messages (push notifications) were built into the UTI Diary App, but it is unclear if these were helpful for the patients or whether patients turned these off manually.

The potential richness of data available through the UTI diary app was also an important factor when designing this app. The findings from the UTI Diary app identified differences in prospective and retrospective reporting of severity of symptoms. Patients recalling severity of symptoms retrospectively (via online survey), were more likely to rate them as severe compared to those who were asked to rate symptoms in real-time (via UTI diary app).

Similarly, this feasibility study showed little or no association between type and severity of symptoms and antimicrobial treatment as the majority of patients received an antimicrobial prescription (72% UTI diary app 95% online survey). Most patients seem to visit their GP around the peak of symptom severity. Irrespective of treatment, most patients improved within one or at the most two days. This seems to suggest that symptoms improve before the

antimicrobial, treatment can have an effect, which is suggested to take 24-48 hours. Although the sample size is too small to draw conclusions from this data, it highlights avenues for further research. These issues should be further examined in the Randomised Control Trial (RCT) setting where the combination of the UTI diary app within an RCT comparing antimicrobial and symptomatic treatment will provide further insight.

Data Analysis

All data was automatically uploaded to an encrypted server which the researcher could access. This made the analysis process more efficient and as data was received in real time the researchers could observe the uptake of the various data collection methods.

To our knowledge, no other studies have captured data on patient symptoms, treatment and duration of symptoms using a text message survey or smartphone application. The UTI Diary app captured data in real time allowing researchers to track the progression of a UTI from consultation to symptom free.

Data presented in this feasibility study is limited and results should guide further research. However, even though sample size was limited, the results are intuitive, real-time data can be used to capture a greater understanding of actual severity and symptoms compared to other methods. The impact of antimicrobial prescribing on duration or severity of symptoms could not be established due to the small sample size but the results may indicate that antimicrobial treatment is not always necessary.

Participants could turn off reminder messages resulting in incomplete diary entries. However, this feasibility study showed that the collection of patient data through smartphone applications is feasible and highly effective to collect real-time data on the natural course of the infection, subject to treatment. Participants should be made aware of the importance of

daily entries when downloading the app and this should be part of the education for both the GP and patient.

Conclusion

Due to the response rate associated with the UTI smartphone app within this feasibility study, it is difficult for the authors to conclusively outline how text messaging apps can help improve patient outcomes. This feasibility study however does identify the potential for bridging the gap between data collection from patients recruited from multiple research sites in clinical studies and disseminating the results to improve clinical practice. This feasibility study highlights that when a patient begins to engage with a data collection method related to their illness, in this case text messaging or a smartphone app, they are likely to continue to do so in the end. In this case by collecting patient data in real time through mobile methods this study highlights the potential of monitoring the symptoms of patients with acute, short lived illnesses, data which has been difficult to capture in the past due to minimal interaction with the patient after their initial consultation. This knowledge highlight the potential of capturing patient symptom data in real time in the future within clinical setting, with the possibility of opening up a dialogue between patients and GP.

Retrospective accounts of illnesses are often used in primary care to diagnose illnesses. There are no studies to our knowledge that report real time versus retrospective reporting of symptom type and severity for UTI. A study comparing real time reporting of schizophrenic patients used mobile devices to provide real time data on their symptoms for 7 days. The same patients were then asked to complete a survey. Their results showed that retrospective accounts through surveys captured average ratings only and surveys were unable to capture variability of symptoms over time [16]. This feasibility study showed similar trends, however, more research is needed to investigate this further.

Symptom diaries for lower respiratory tract infections have been shown to be easy to use for measuring symptoms and treatment effects [17]. Diaries have also been used in the past to investigate natural course and treatment options for UTI. In Little *et al*'s (2010) study only 64% of participants returned complete symptom diaries[18]. The bias of incomplete data could be avoided with an app which electronically extracts data entries each day. In another study on antimicrobial use in UTI, researchers used follow up telephone calls three days after initiation of treatment to remind patients to complete their diaries. Patients also received a follow up call 28 days to remind them to complete the survey and return a urine sample [19]. These methods are labour intensive and biased due to retrospective recording of symptoms and treatment remains an issue.

Within a recent RCT comparing antimicrobial with symptomatic treatment a diary was used to measure severity of symptoms and treatment compliance [20]. However, to maximise data collection and quality, they involved study nurses to make telephone calls at day 1, 3, 5 and 7 to record symptoms and treatment[21]. Even though it improved data quality, this cost can potentially be saved with the use of the UTI diary app, in which reminders and pop-ups can help patients record their symptoms and treatment.

It has been shown that electronic diaries (palm held devices) with enhanced compliance features were more effective method of collecting information in comparison with paper based diaries for chronic pain [22]. This study showed that compliance with paper based diaries was poor compared to electronic diaries, patients did not complete their paper based diaries in a timely fashion (i.e. backfilling diaries) introducing bias due to retrospective recall and systematic bias due to the self-selection of completion times. To reduce any retrospective recall bias, diaries should be completed close to the time of the event they are trying to measure (i.e. antibiotic consumption) [23].

The ubiquitous use of smartphones provides opportunities to collect high quality, real-time data through easy to use apps. Paper based surveys can also be cumbersome and inconvenient to access depending on their design. Apps have been shown to be acceptable for patients and to save time and money in health research.

DECLARATIONS

Ethics approval and consent to participate

Ethical approval for this study was granted by the ICGP as part of the broader SIMPle study.

Consent to publish

All participants consented to participating in this research and agreed that their aggravated anonymised may be used in reporting results.

Competing interests

The authors have no competing interests to declare.

Authors Contribution

SD coordinated the design of both the text message and UTI Diary App workflows. SD also drafted the manuscript along with AV who conceived the SIMPle study. MT cleaned and conducted the statistical analysis as part of this paper. All authors were involved in conceptualising the study and reviewing the manuscript.

Availability of data and materials

The dataset supporting the conclusions of this article are available upon request to the authors.

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List of abbreviations

Randomised Control Trial: RCT

SIMPle: Supporting the improvement and management of urinary tract infections

Smartphone Application: App

Urinary Tract Infection: UTI

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