Investigating the behavioural effects of a mobile telehealth intervention in people with insulin-requiring diabetes: results of a randomized controlled trial with patient interviews

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ABSTRACT

Introduction: Evidence supporting telehealth effects on clinical outcomes in diabetes is available, yet mechanisms of action for these improvements remain poorly understood. Behavioural change is one plausible explanation as telehealth involves several behaviour change techniques. This study investigated the behavioural effects of a mobile-phone based telehealth intervention in people with diabetes.

Methods: A randomized controlled trial compared standard care, to standard care supplemented with mobile telehealth (MTH) (self-monitoring, data transmission, graphical and nurse-initiated feedback, educational calls). Self-report measures of self-efficacy, illness beliefs, and self-care were repeated at baseline, 3 and 9 months. MTH effects were based on the Group by Time interactions in hierarchical linear models and effect sizes with 95% confidence intervals (CIs). Interviews with MTH participants explored the perceived effects of MTH on diabetes management.

Results: Eighty-one participants were randomized to the intervention (n=45) and standard care (n=36). Significant Group by Time effects were observed for five of seven self-efficacy subscales. Effect sizes were large, particularly at 9 months. Interaction effects for illness beliefs and self-care were non-significant, but effect sizes and confidence intervals suggested MTH may positively affect diet and exercise. In interviews, MTH was associated with increased awareness, motivation, and a greater sense of security. Improved self-monitoring and diet were reported by some participants.

Conclusion: MTH empowers people with diabetes to manage their condition and may influence self-care. Future telehealth research would benefit from investigating behavioural mechanisms and determining patient profiles predictive of greater behavioral effectiveness.

INTRODUCTION

Suboptimal adherence to recommended diabetes self-care behaviours is a well-recognized problem (1-4). Adherence rates have been found to be 10%- 80% for long-term exercise (1;5), 35-37% for diet (5), 64-70% for self-monitoring of blood glucose (BG) (5), and 71-72% for appointment keeping (5). This has implications for the successful achievement of clinical targets, which for glycosylated hemoglobin (HbA1c) and blood pressure (BP) for example, are not reached by 40%-60% of people with diabetes (6;7).

Telehealth is defined in this paper as the person with diabetes' use of technology to record and transmit data to health care professionals and receive feedback. Telehealth provides health care professionals with the ability to provide timely care, detect early signs of deterioration, and identify/monitor closely high risk patients. Reviews of these interventions in people with diabetes suggest that they result in improvements in HbA1c (8-10) and that they are well received by patients (11).

In addition to supporting clinical care, telehealth aims to improve treatment adherence (12). Self-monitoring and feedback are the hallmark of telehealth (13). These behaviour change strategies have successfully changed peoples' behaviours (14-18) by improving their confidence in managing their health (*i.e.* self-efficacy) and the way they think about it (*i.e.* self-regulation) (19). Education/information is another behaviour change strategy integrated to many telehealth interventions. It is sometimes considered a secondary feature of telehealth (20) as real-time education via feedback (21) is dependent on clinical data transmission. Despite the potential for telehealth to influence diabetes self-care, few studies measure these effects. Only three (17.7%) of twenty-six ‘telediabetes’ studies were found to report on the effects of telehealth on self-care (*e.g.* carbohydrate counting, physical activity) in a recent review (12).

Studying the effects of telehealth on self-care would not be complete without understanding pathways of change. Research recommendations have underlined the need to understand these causal mechanisms (22). Such investigations are likely to be facilitated by use of theory. Theories of health behaviour propose that beliefs (*e.g.* beliefs/knowledge about the condition or the performance of the behaviour), attitude, and expectations (*e.g.* efficacy or outcome expectations) drive behaviour (23) and act as mediators of behaviour change. So far, little research has investigated pathways of behavioural change in telehealth. One review (24) examined the effects of telehealth on two mediators of behaviour change, *i.e.* knowledge and self-efficacy. The small number of studies presenting evidence on these effects however, combined with their poor methodological quality, made conclusions difficult to reach.

We have reported the effects of an RCT-based evaluation of telehealth on clinical outcomes in diabetes (25). Primary (HbA1c) and secondary clinical outcomes (BP, insulin dose, diabetes outpatient appointments) were not significantly affected by the intervention. The current paper reports on the more proximal effects of this RCT on mediators of behaviour change (self-efficacy and illness beliefs) and diabetes self-care. The selection of these behavioural outcomes was guided by Social Cognitive Theory (26) and Self-Regulation Theory (27). It was hypothesized that telehealth would result in improvements in self-efficacy, illness beliefs, and diabetes self-care. Interview data collected on participants' perception of the behavioural effects of telehealth is also included in this paper as they help interpret the quantitative findings.

METHODS

Study Design

This study used a RCT design to compare standard care supplemented with a mobile-phone telehealth intervention, *i.e.* mobile telehealth (MTH), to standard care alone. Semi-structured interviews were conducted with participants after the MTH intervention to help interpret the quantitative findings. Ethical approval for this study was gained.

Setting and participants

The study was conducted in the diabetes unit of a secondary health center in a multiethnic borough of London, United Kingdom (UK). Based on a power calculation detailed in the published protocol (28), the aim was to recruit 248 participants. Participants were adults with poorly controlled type 1 or type 2 diabetes (most recent HbA1c had to be taken in the last 12 months and above 7.5%). Their level of English needed to be adequate. Patients requiring district nurse home visits for BG monitoring and insulin administration were excluded, as well as those with prior MTH experience, visual or dexterity problems, or those who travelled regularly outside the UK (3 weeks or more). A diagnosis of kidney failure, sickle cell disease, or severe mental health illness resulted in exclusion from the study, as did pregnancy.

Recruitment and randomization

Potentially eligible participants were met by a researcher after their outpatient appointment. Full eligibility was verified. Interested participants signed a consent form, and received a baseline questionnaire and a pre-stamped envelope for return. Once completed, participants were randomized to the intervention or control group (standard care) using an online sequence generator that generated blocks of 20. A separate consent form was signed prior to the interview.

The MTH intervention

Intervention participants received the MTH equipment and training to transmit diabetes-related data (*i.e.* BG and BP readings, time since last meal, level of physical activity performed, insulin dose, and weight) to a MTH nurse for feedback. Automated and colour-coded graphical feedback on clinical readings (BG and BP) was displayed on the mobile-phone whenever new entries were recorded. These graphs compared the most recent clinical reading to those recorded in the last 5 and 30 days. Each colour represented a different glycaemic state (blue: hypoglycaemia, green: normoglycaemia, amber: borderline hyperglycaemia, red: hyperglycemia). The monitoring protocol (28) included feedback on out of range clinical readings, support for insulin titration, and education on lifestyle changes (six weekly educational calls). Participants requiring substantial medication adjustments were encouraged to schedule an appointment with their diabetes specialist nurse. MTH participants continued to receive standard care which consisted of one follow-up appointment with the diabetes specialist nurse every 3-4 months and 1-2 annual appointments with the diabetes consultant. A diabetes specialist nurse was available during working hours to respond to patients' urgent queries.

Measures

Behavioural outcome data was collected at baseline, 3 and 9 months using questionnaire measures with adequate psychometric properties (29-33). Follow-up questionnaires were mailed to participants with a pre-stamped return envelope.

Self-efficacy

Two subscales of the Health education impact Questionnaire (HeiQ, v3.0) (34) were used to measure empowerment. The Self-Monitoring and insight subscale measures beliefs in one's ability to monitor the physical and/or emotional responses for appropriate self-management. The Skills and Technique Acquisition subscale measures one's beliefs in the knowledge-based skills and techniques acquired to self-manage health. Respondents indicated their level of agreement with each item using a six point Likert scale. Higher mean subscale scores indicated greater self-efficacy.

The Insulin Management Diabetes Self-Efficacy Scale (IMDSES) (31) measures diabetes-specific self-efficacy on subscales relating to general management, insulin, diet , exercise, and foot-care . A six point Likert scale was used with higher scores indicating greater self-efficacy. One item on food exchange was removed as this concept is not commonly used in the UK ('I can correctly exchange one food for another in the same food group').

Illness beliefs

The Personal Models of Diabetes (PMD) scale assesses beliefs on perceived seriousness of diabetes as well as beliefs on the perceived effectiveness of the treatment to control diabetes and prevent complications (35). A five point Likert scale was used with higher mean subscale scores indicating stronger endorsement of these beliefs.

Diabetes self-care

The Summary of Diabetes Self-Care Activities (SDSCA) (33) assesses the number of days in a week (0-7) on which participants engaged in general diet , fruit and vegetable intake, fat intake, exercise, foot care, and BG testing. Higher mean subscale scores indicated greater frequency of self-care behaviours. The SDSCA does not differentiate between participants who self-monitor BG once or more than once each day. An item to capture this information as free text was added into the survey ('How many times approximately do you measure your blood glucose levels in one week?').

Interview Topic Guide

The interview guide included a question on the perceived effects of the MTH on diabetes self-management. Participants were asked 'To what extent has the use of MTH influenced the way you self-manage your diabetes?’. Other areas of interest were covered (28), findings for these will be published separately.

Data analysis

Quantitative data were analyzed using an intention-to-treat principle. Baseline differences were checked using independent Student t-tests and Chi-Square tests. Intervention effects were examined using hierarchical linear models (HLM). Random effects accounted for within-participant correlation, and a first order autoregressive covariance structure was used. Baseline differences were adjusted for (fixed effects). Interactions between Group and Time (fixed effects) were used to identify differential treatment effectiveness. Hedges g standardized effect sizes for mean group differences at follow-up were computed with 95% confidence intervals (CIs). Significance was set at $p<0.05$.

Audio-recordings of interviews were transcribed verbatim, de-identified, and imported into Nvivo (v10.0) for analysis. Step-to-step recommendations for thematic analysis were followed (36). One researcher coded all transcripts. A second researcher independently coded two transcripts to help discuss emerging themes. Once analysis of all transcripts was complete, these two researchers met again to finalize the qualitative analysis.

RESULTS

Sample characteristics

Eighty-six participants consented to the study. Eighty-one were randomized to the intervention (n=45) and control (n=36) groups after returning the baseline questionnaire. Just over half (56.8%) were male. Mean age was 57.2±13.6 years (range: 20.3-84.4) and the majority of participants (65.4%) had no formal education or no further than GCSE/O'levels. Seventy-six percent were non-White. Mean number of years with diabetes was 16.6±7.7 (range: 1.8-43.7) and the majority (87.7%) had type 2 diabetes. Intensive insulin therapy (≥3 daily injections) was prescribed to half (53.1%) of participants. Mean HbA1c (%) was 9.1 ± 1.8 in the intervention group and 8.9 ± 1.7 in controls. The majority were overweight (25.9% with a body mass index

[BMI] ≥ 25 kg/m^2) or obese (56.8% with a BMI ≥30 kg/m^2). Gender was the only statistically significant difference (p=0.013) between interventions (68.9% male) and controls (42.7%).

Attrition

There were four dropouts (3 interventions, 1 control), and two deaths (1 intervention, 1 control). Two participants failed to complete the 3 month questionnaire (2 controls) and five the 9 month questionnaire (2 interventions, 3 controls). Data were not imputed for missing questionnaires. Survey data were available for 81 participants at baseline (45 interventions, 36 controls), 74 at 3 months (41 interventions, 33 controls), and 70 at 9 months (39 interventions, 31 controls).

Intervention effects on self-efficacy and illness beliefs

Table 1 presents the adjusted estimated marginal means from the HLM models to examine the effects of MTH on self-efficacy and illness beliefs. Group by Time interactions were significant. for four of five diabetes specific self-efficacy subscales (general management, p=0.010; diet, p=0.049; insulin, p=0.017; foot care, p=0.017) and for one of two HeiQ subscales measuring a more generic health self-efficacy (Self-Monitoring and Insight, p=0.010). Effect sizes for these mean group differences at 3 and 9 months were moderate to large (-0.27 and -0.65), with magnitudes generally increasing over time. Whilst some of the respective 95% CIs crossed zero for 3 month differences, none of them did at 9 months, lending further support to the existence of an intervention effect on self-efficacy at this time point.

Although the Group by Time interaction effect for the second HeiQ subscale on Skills and Technique Acquisition was not significant, the effect size for this mean group difference at 9 months was large (-0.50) and the 95% CI did not cross zero. This suggests the intervention may have had an effect on this subscale. The non-significant *p*-value for the interaction effect may have been caused by lack of power.

In contrast, none of the Group by Time interaction effects for illness beliefs were statistically significant. Effect sizes for mean differences at 3 and 9 months were small (-0.02 and -0.23) and crossed zero.

Intervention effects on diabetes self-care

Table 2 presents the adjusted estimated marginal means from the HLM models to examine the effects of MTH on diabetes self-care. None of the Group by Time interaction effects were significant. Effect sizes for mean group differences were large for the exercise subscale at 3 months and the general diet subscale at 9 months (-0.47 and -0.54, respectively), with 95% CIs not crossing zero. The intervention may have influenced these self-care activities, but lack of power may have prevented p-values for these effects from reaching significance.

Table 1. Changes in self-efficacy and illness beliefs in the intervention and control groups

Measures	Intervention (mean ± SD)	Control (mean ± SD)	*F*-statistic, *p*-value for Group (2) x Time (3)	Effect size for group differences at 3/9 months (95% CIs)
IMDSES-General management			$F_{2.120.38}$= 4.79, *p*=0.010*	
Baseline	27.78±5.98	27.58±5.85		-
3 months	29.79±5.89	26.31±5.80		-0.58 (-1.04,-0.12)
9 months	29.66±5.81	25.83±5.68		-0.65 (-1.13,-0.17)
IMDSES-Diet			$F_{2,112.38}$=3.10, *p*=0.049*	
Baseline	23.44±6.76	23.84±6.61		-
3 months	24.79±6.64	22.92±6.49		-0.28 (-0.73, 0.18)
9 months	25.26±6.57	22.11±6.43		-0.47 (-0.94, 0.00)
IMDSES-Insulin			$F_{2,115.43}$=4.19, *p*=0.017*	
Baseline	40.67±8.70	40.50±8.50		-
3 months	41.43±8.52	39.14±8.32		-0.27 (-0.72, 0.19)
9 months	44.81±8.40	39.77±8.32		-0.59(-1.06, -0.11)
IMDSES-Exercise			$F_{2,115.51}$= 0.19, *p*=0.827	
Baseline	7.28±2.78	6.54±2.72		-
3 months	7.36±2.74	6.25±2.68		-0.40 (-0.86, 0.06)
9 months	7.36±2.52	6.37±2.67		-0.37 (-0.84, 0.10)
IMDSES-Foot care			$F_{2,122.617}$=4.24, *p*=0.017*	
Baseline	9.42±2.56	9.91±2.51		-
3 months	10.05±2.53	9.34±2.49		-0.28 (-0.73, 0.18)
9 months	10.36±2.52	8.94±2.48		-0.55 (-1.03, -0.08)
HeiQ-Self-monitoring and insight			$F_{2,140.31}$=4.77, *p*=0.010*	
Baseline	4.77±0.75	4.74±0.74		-
3 months	5.00±0.74	4.76±0.72		-0.32 (-0.78, 0.14)
9 months	5.05±0.72	4.57±0.71		-0.65 (-1.13, -0.17)
HeiQ-Skills and technique			$F_{2,126.08}$=1.92, *p*=0.151	
Baseline	4.52±0.98	4.40±0.96		-
3 months	4.56±0.97	4.45±0.95		-0.11 (-0.57, 0.34)
9 months	4.72±0.96	4.23±0.94		-0.50 (-0.98, -0.03)
PMD-Seriousness			$F_{2,97.26}$=0.59, *p*=0.558	
Baseline	3.35±0.84	3.22±0.82		-
3 months	3.13±0.82	3.11±0.80		-0.02 (-0.48, 0.43)
9 months	3.16±0.82	2.97±0.80		-0.23 (-0.70, 0.24)
PMD-Treatment effectiveness			$F_{2,144.91}$=0.36, *p*=0.698	
Baseline	4.29±0.66	4.29±0.65		-
3 months	4.31±0.66	4.21±0.64		-0.15 (-0.60, 0.30)
9 months	4.38±0.64	4.27±0.63		-0.17 (-0.64, 0.30)

Abbreviations: IMDSES- Insulin Management Diabetes Self-Efficacy Scale; HeiQ - Health education impact Questionnaire; PMD- Personal Models of Diabetes; SDSCA- Summary of Diabetes Self-Care Activities. CI- Confidence Intervals.

Notes: Higher scores indicate greater self-efficacy or endorsement of beliefs; * indicates significant interaction effects

Table 2. Changes over time in diabetes self-care in the intervention and control groups

Measures	Intervention (mean ± SD)	Control (mean ± SD)	*F*-statistic, *p*-value for Group (2) x Time (3) interaction	Effect size estimate for group differences at 3/9 months with 95% CIs
SDSCA- General diet			$F_{2.108.63}$=2.78, *p*=0.067	
Baseline	4.63±1.83	4.65±1.81		-
3 months	5.24±1.81	5.23±1.78		-0.01 (-0.46, 0.45)
9 months	5.31±1.82	4.31±1.78		-0.54 (-1.02, -0.07)
SDSCA- Fruit and vegetable			$F_{2.105.59}$=1.61, *p*=0.204	
Baseline	4.57±2.17	4.79±2.12		-
3 months	4.71±2.15	4.62±2.09		-0.04 (-0.50,0.41)
9 months	4.84±1.89	4.14±2.07		-0.35 (-0.82, 0.12)
SDSCA- Fat intake			$F_{2.118.78}$=0.06, *p*=0.939	
Baseline	4.49±1.82	4.40±1.79		-
3 months	4.58±1.82	4.62±1.77		0.02 (-0.43, 0.48)
9 months	4.86±1.79	4.77±1.76		-0.05 (-0.52, 0.42)
SDSCA- BG monitoring			$F_{2.113.49}$=0.61, *p*=0.826	
Baseline	4.86±2.04	5.62±2.00		-
3 months	4.67±2.01	5.13±1.97		0.23 (-0.23, 0.68)
9 months	4.60±1.99	4.82±1.95		0.11 (-0.36, 0.58)
SDSCA- Exercise			$F_{2.125.01}$=2.03, *p*=0.135	
Baseline	2.78±2.10	2.73±2.06		-
3 months	3.09±2.07	2.10±2.03		-0.47 (-0.93, -0.01)
9 months	3.12±2.05	2.38±2.02		-0.35 (-0.82, 0.12)
SDSCA- Foot care			$F_{2.\ 102.76}$=0.36, *p*=0.701	
Baseline	3.43±2.58	3.76 ±2.52		-
3 months	3.73±2.52	3.69±2.46		-0.02 (-0.47, 0.44)
9 months	3.79±2.50	3.77±2.44		-0.01 (-0.47, 0.46)
Weekly frequency BG monitoring*			$F_{2,134.68}$=1.04, *p*=0.312	
Baseline	10.31±15.76	9.19±15.55		-
3 months	9.74±15.71	11.39±15.51		0.10 (-0.35,0.56)
9 months	13.68±16.66	11.29±15.52		-0.14 (-0.61,0.32)

Abbreviations: SDSCA- Summary of Diabetes Self-Care Activities; BG- blood glucose.
Notes: Higher scores indicate greater frequency of self-care behaviours. *Individual item added intoSDSCA survey

Themes from qualitative data

Forty MTH participants completed the intervention and 26 (65%) agreed to be interviewed. Four themes on the perceived effects of MTH on diabetes self-management emerged (see Table 3 for supporting quotations).

Theme 1: Increased awareness

Participants reported an increased awareness of the extent to which they controlled their diabetes. Visualizing the graphical feedback increased participants' awareness of trends in BG. This allowed them to see 'the bigger picture' and to position their overall level of diabetes control on a continuum from poor to good. The colour-codes were reported to facilitate the identification of time periods when tighter control of BG readings was needed. They also prompted participants to think about the reasons behind fluctuations in BG and participants reported a heightened awareness of the factors influencing diabetes control.

Theme 2: Increased motivation

Participants reported that MTH was an opportunity to think about making changes to their diabetes self-management. The graphical feedback in particular was considered to act as an incentive to improve BG readings. Combined with the awareness that a MTH nurse was available to monitor their readings, participants felt that controlling their BG had become a personal challenge. Some used the average of BG readings in the automated feedback to try 'to beat that average for a better average next time'. MTH acted as a reminder to self-care in moments of behavioural slippage.

Theme 3: Influence on diabetes self-care

Self-monitoring of BG was the behaviour the most frequently reported to have increased. This was because receipt of graphical feedback and knowledge that someone reviewed their data was considered to add 'purpose' to this behaviour. Some participants also reported improvements in dietary intake through reductions in portion sizes and snack consumption. In fewer cases, MTH was reported to increase adherence to insulin (*i.e.* fewer missed dosages) or to insulin adjustments.

A minority of participants reported no benefits from MTH on self-care. They tended to be dissatisfied with the MTH nurse feedback, to not use the graphical feedback, or to consider their diabetes control as adequate.

Theme 4: Perceived sense of security

Most participants experienced a heightened feeling of security and safety because they believed that someone to whom they were '*directly in some mysterious way connected with*' was watching over their BG readings. The knowledge that someone was '*in the background*' to check BG readings and prevent acute complications created a peace of mind. Two participants compared MTH with '*Big Brother'*, a reality television show involving continuous monitoring of participants.

Table 3. Themes from qualitative enquiry on perceived effects of mobile telehealth

Theme 1: Increased awareness	
.. of level of diabetes control	*"Actually it was really good because then it gives me an idea of what group that I fall in. Mostly I see that I am in the yellow, but I should be green and sometimes, I am in the red which is not too good for me, but um.. It really does help for you to see."* (Female patient, 33 years)
.. of factors influencing diabetes control	"*I mean I can see things and change, I get quite annoyed with myself when I see the reading go up, so I start investigating what have I been doing that's done that. Now this is the opportunity that you've got with this system, that you wouldn't have any other way*." (Male patient, 73 years).
Theme 2: Increased motivation	
MTH is a motivational tool/ personal challenge	*"You know, because all the information is there [..] Then psychologically you are handling it - I should do more exercise, I should eat less fat, or sugar, or salt, these things you know. That can lead you to those aspects you know."* (Male patient, 70 years) *"So let me tell you on the positive side, this is my health. Somebody is helping me to do it. I need to prove, so it became a challenge to me."(*Male patient, 48 years*)*
Theme 3: Influence on self-care	
Increased monitoring of BG	*'Sometimes I do, I did, but since I've got this [patient shows the phone], I do it more often. I do it more often because sometimes I go..I'm going out and I don't bother, but with this because I know it will be recorded..*" (Male patient, 71 years)
Dietary changes	"*Well the feedback I'm getting now.. Before I just couldn't be bothered, I would eat anything. Now I think, I think I'm more cautious of what I can and cannot eat, or the portion that I can have*" (Female patient, 33 years)
Improved insulin intake and adjustments	"*It does make a difference, it's made me think that I've got to keep to it...I've got to keep it down, I've got to keep it even. No ups and downs. You know if it goes up I give a bit more insulin, see if I can make it come down*." (Male patient, 69 years)
Theme 4: Perceived sense of security	
Someone there to monitor my clinical readings and prevent complications	"*You know where you have regular readings going through to somebody and euh.., you know at least, if something happens, you know that somebody is monitoring, you know. Though I didn't have much contact with [name of telehealth nurse], at the back of my mind I had that peace of mind, which I knew that if something was really drastically wrong, they would get in touch with me because somebody was looking at my readings*." (Male patient, 53 years)

DISCUSSION

This section discusses the effects of MTH on self-efficacy and illness beliefs, and on diabetes self-care using findings from the quantitative and qualitative enquiries.

Intervention effects on self-efficacy

Results of the RCT suggest that MTH significantly improved self-efficacy. These effects were consistent across several generic and disease-specific subscales, and increased over time. Although no minimal clinically important differences are known for these measures, the consistency across subscales is encouraging. Only 5 of 21 papers included in a review of mobile-phone interventions for patients with diabetes (37) were reported to measure self-efficacy. Where evaluated, it has often been positively influenced by MTH (38-42). These results are in line with the suggestion that self-monitoring and feedback influence self-efficacy (19). Self-efficacy is considered to determine motivation (43) or to reflect levels of motivation (44). The increased motivation reported by MTH participants in the interviews therefore offers further support to the quantitative effects of MTH on self-efficacy. This complementarity of the qualitative and quantitative data suggests that findings on MTH effects on self-efficacy are robust.

Intervention effects on illness beliefs

Few MTH studies have included an assessment of illness beliefs. Results from this RCT suggested that MTH did not influence beliefs on the perceived seriousness of diabetes or on treatment effectiveness to control diabetes and prevent complications. These quantitative findings were supported by the absence of themes relating to these beliefs in the qualitative data on perceived effects of MTH. Another mobile-phone intervention also failed to influence beliefs on the likelihood for long-term complications (45). Personal models of diabetes have been found to be relatively stable over time (46) and this may limit intervention effects. Also, the intervention did not formally include behavioural skill training, a suggested strategy to influence illness beliefs (47). Finally, the non-significant intervention effects on personal models of diabetes may be related to a ceiling effect. Means at baseline indicated that participants considered diabetes to be ‘fairly’ to ‘very’ serious and the prescribed treatment regimen to be ‘very’ to ‘extremely’ effective to control diabetes and prevent complications. In contrast, the qualitative data suggested that MTH increased participants’ awareness of their level of diabetes control and of the factors associated to it. This suggests that MTH may positively influence beliefs relating to these aspects of self-management rather than to those assessed in this study. Further research may benefit from including a measure to capture these beliefs.

Another type of health belief that MTH is likely to influence according to the qualitative data from our study relates to perceived security. This belief was not measured as an outcome in the RCT. There was evidence however from the interviews that MTH made participants feel safer because clinical staff monitored their clinical readings and could help prevent acute complications. In this context, the construct of perceived security is akin to perceived susceptibility (one's perception of the risk or the chances of contracting a health condition/complication). Perceived susceptibility is a component of the widely used Health Belief Model (48) and is considered one of the health beliefs with the greatest influence on behaviour. The qualitative findings from our study suggest that MTH may result in a decrease in perceived susceptibility. These findings are in line with some concerns that telehealth may reinforce power relationships and encourage patients to be passive and dependent (49-51).

Intervention effects on diabetes self-care

Results from the Group by Time interactions suggested that MTH did not influence diabetes self-care. The evidence available from quantitative studies on the impact of telehealth on diabetes self-care is mixed. Some studies have found telehealth to improve diabetes self-care (39;52) whilst others have not (41;53-55). Several reasons for this conflicting evidence are possible. First, inconsistencies in findings could be due to the measurement of adherence which is customarily self-report in these studies (56). Self-report measures of adherence differ in their content and in response options (57). They are also prone to bias, and none of the studies mentioned above - including ours - have used multiple measures of adherence or cross-validated self-report measures with objective data (56). Novel approaches such as mobile-phone and computerized logbooks for ecological momentary assessments are superior to self-reported adherence (58) and may be particularly feasible to implement in MTH (57). Physical activity data in particular is becoming easier to capture objectively with Smartphones and wearable sensors (59). These measurement methods were less easily available or affordable when this study was designed.

Despite the lack of statistically significant Group by Time interaction effects on self-care, several of the participants interviewed reported improvements in their diet and BG self-monitoring frequency. Such effects have been reported in other qualitative studies (60-63). These findings suggest that benefits from MTH may have been experienced by some, but not all, participants. Importantly though, effect sizes and CIs in the quantitative data did suggest a MTH effect on general diet at 9 months, confirming patterns in the qualitative data. Taken together, these findings underline the importance for effect sizes and CIs to be considered alongside p-values when interpreting quantitative data (64), and illustrate how qualitative enquiries can complement and nuance quantitative findings. The variation in MTH effects on self-care across participants supports the need for further research to identify the combinations in which context, mechanisms, and outcomes interact to promote effectiveness (54), as well as the patient characteristics associated with greater behavioural change in MTH.

The relationship between self-efficacy and self-care

Social Cognitive Theory postulates that there is linear relationship between self-efficacy and behaviour. This theory is often used to design mobile-phone interventions (65), but few studies have assessed both these constructs. Those that have assessed both, either found improvements in self-efficacy only (38;41) or in both constructs (39).

The above inconsistencies have led some researchers to question the importance of self-efficacy as a health outcome (66). The protocol for this study included a statistical analysis plan to examine the mediating effect of self-efficacy on self-care (28). Significant changes in mean self-care scores were required for these analyses to be conducted however. As these were not observed, this study's contribution to our understanding of the dynamics between self-efficacy and self-care is less than expected.

One of the possible reasons why improvements in self-efficacy did not translate to self-care is duration of follow-up. The time period necessary for these translations may vary according to a range of factors including MTH intervention content (*e.g.* intensity of health care professional support and feedback, behaviour change techniques involved), participants' characteristics (*e.g.* baseline self-efficacy and self-care, disease severity) and technology usage (*e.g.* frequency of transmissions). The nine month follow-up in the current study may not have been sufficient for improvements in self-care to occur across a majority of intervention participants. Behaviour changes may occur more rapidly in some participants, as the qualitative data on dietary and self-monitoring changes suggests. Also, other factors not accounted for in Social Cognitive Theory may interfere with self-efficacy translating into behaviour change. The decrease in MTH participants' perceived susceptibility mentioned above is one example. Other examples include personality, subjective norms, and cultural factors.

Limitations

The main drawback of this study is the sample size for the RCT. The challenges experienced during recruitment (67) led to lack of power, underlining the need for RCT findings to be interpreted with caution and limiting the number of statistical analyses. A larger sample size may have yielded different results, and greater precision of estimates. The parallels observed in the quantitative and qualitative findings however do suggest that these findings are reliable. They also emphasize the value of combining these two methods to provide richer interpretations.

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Guarantor. SN

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