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Challenges in Patient Recruitment and Intervention Delivery in a Mobile Telehealth Study

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ABSTRACT

Introduction: Mobile telehealth (MTH) evaluations in diabetes have been conducted, but few report detailed data on recruitment and intervention delivery and fidelity, when these are aspects of research with important implications. This paper reports these data from a MTH study and describes the challenges to recruitment and delivery that were experienced.

Methods: We conducted a mixed methods MTH study that included a 9-month randomized controlled trial in people with poorly controlled diabetes. Restrictions to access research participants were documented, as well as reasons for exclusions and refusals. Data on contacts between MTH participants and the MTH team were used to report on intervention delivery and fidelity.

Results: The recruited sample size represented 6% of the total clinic population (n=1360) and 10.7% of the number of potentially eligible people at the clinic (n=802) identified at the beginning of the study. Contextual factors related to patients, health care providers, the institution, or the recruitment protocol, contributed to the high selectivity of the sample. Technical and device-related aspects of the intervention were delivered successfully but the education and clinical feedback by the MTH nurse were not. Thirty-seven (92.5%) of 40 introductory calls, 32 (13.3%) of 240 educational calls, and only 23 telephone calls for clinical feedback were made by the MTH nurses. Changes to the MTH nursing staff contributed to this low fidelity.

Discussion. The current paper underlines the influence contextual factors may have in the conduct of health care research such as MTH, and underlines the need for intervention fidelity to be assessed and reported.

INTRODUCTION

A large amount of research has been conducted to evaluate the effectiveness of mobile telehealth (MTH) in people with diabetes, and reviews have concluded MTH is likely to hold benefits for diabetes management (1-5). Process evaluation frameworks (6) underline the importance of reporting on recruitment (procedures used to attract participants, barriers and facilitators, reasons for non-participation), implementation (the extent to which the intervention has been delivered and received by the intended audience), fidelity (the extent to which the intervention was delivered as planned), and context (aspects of larger social, political, and economic environment that may influence the study). These aspects of research are rarely reported in MTH studies, despite their significance and their influence on MTH feasibility, costs, and outcomes.

Data on the recruitment process during which potential participants are identified, approached, and enrolled provides valuable information for researchers on study design and planning, resource allocation, acceptability of MTH, as well as on the representativeness of the study sample, which influences the study's external validity. This has important implications for the scalability of telehealth, as understanding the generalizability and applicability of study findings to other settings, organizations, or populations (9) can support health policy decision-making. Information on recruitment in MTH studies may be particularly useful because failure to reach targeted sample size (7), and lack of power are recognized problems in telehealth research (8).

The need for data on intervention delivery to be reported in MTH studies has been underlined (10). Data on MTH transmissions and contacts are provided in a minority of studies (11;12). They remain minimal, and often are not compared to intervention protocol requirements to reach conclusions on intervention fidelity. Intervention fidelity is considered a prerequisite for a valid and methodologically sound evaluation (13) as it provides some information on a study's internal validity, and this can inform translation into practice.

Contextual factors are barriers or facilitators to the study that exist prior to, or that emerge during, implementation (15;16). They can be internal or external to the intervention, and they can interact with an intervention in complex ways, impacting generalizability and moderating study outcomes (15;16). Early work has summarized some of the factors affecting telehealth implementation (Saliba et al., 2012). A better understanding of these influences is necessary to improve the currently disappointing success rates of telehealth projects (18).

The aim of the current paper is to report a process evaluation for a MTH randomized controlled trial (RCT) focusing on recruitment, implementation, fidelity and context, and the relationships between these. Although implementation can refer to both intervention delivery and receipt (Linnan and Steckler et al., 2002), the current paper focuses on the former since the latter (i.e. MTH usage) is described in another paper (19).

METHODS

The methods used to report on recruitment, intervention delivery, intervention fidelity, and context are described below. The 9-month RCT during which data were collected was conducted in a diabetes clinic in the London borough of Newham, United Kingdom (UK). Details of the study protocol are described elsewhere (19).

Recruitment

In this paper, the term recruitment refers to any procedure aiming to identify and approach potentially eligible people with the aim of enrolling them to the study. There were four main steps to the recruitment process: 1. Identification of potentially eligible patients with an appointment scheduled with a diabetes nurse in the following two weeks (a computer query of medical records was run every two weeks), 2. Invitations sent to potentially eligible people identified in step 1(every two weeks), 3. In person approach of patient after appointment to verify eligibility, and discuss participation, 4. Enrollment to study, if appropriate.

Eligibility criteria are listed in Box 1, and the target sample size was 248 (19). An electronic database was used to record the number of potentially eligible patients identified, number of patients invited to the study, number of patients approached, number of exclusions and refusals, and reasons reported, and number of patients enrolled to the study.

Box 1. Eligibility criteria to the study

Inclusion criteria (extracted during computer query of medical records)
-Poor diabetes control (most recent HbA1c ≥ 7.5%)
-Diabetes (type 1 and type 2)
-Insulin-requiring
-English proficiency
-Attended an appointment at the clinic with a diabetes nurse in the last 12 months, or had a recorded HbA1c in the clinic records in the last 12 months

Exclusion criteria (verified on day of appointment)
-Regular travels outside the UK for 3 weeks or more
- Receipt of district nurse home visits for BG monitoring and insulin administration
-Pregnancy
-Diagnosis of kidney failure or sickle cell disease
- Psychiatric morbidity
- Poor vision/dexterity making the use of MTH difficult, psychiatric morbidity

Intervention delivery

The intervention required MTH participants to use a mobile-phone application software to record and transmit diabetes-related parameters (blood glucose [BG] and blood pressure readings, time since last meal, level of physical activity performed that day, insulin dose, and weight) to a MTH nurse in order to receive live and graphical feedback. The intervention protocol required the delivery of the following components:

a) Technical support and device-related operations: These included MTH training sessions, technical assistance, reminder to transmit (referred to as non-transmission calls), responses to incoming calls, and end of trail calls to notify MTH participants of the upcoming de-activation of their SIM card. With the exception of the MTH training that was conducted by an engineer, these responsibilities were taken on by the technical support team.

b) Clinical advice and feedback by the MTH nurse on out-of-range clinical readings and according to a pre-determined monitoring protocol (19).

c) Patient education and other assistance: The MTH nurse was required to make introductory calls and six weekly educational phone calls to MTH participant, and to respond to incoming calls.

Intervention delivery was assessed using contact data between MTH participants and the engineer, technical support team, and MTH nurse that were extracted from the MTH web-server and from separate records kept by members of the MTH team. Intervention delivery data presented in this paper is for the 40 MTH participants who completed the intervention period.

Intervention fidelity

Intervention fidelity was estimated by comparing intervention delivery data to specific expectations based on the protocol (i.e., each participant required one introductory call, an educational call every six weeks, and an end of trial call). Set expectations for technical assistance and clinical feedback were not possible as delivery of these intervention components was based on participants' needs and clinical judgement rather than on a fixed schedule. For technical assistance, intervention fidelity was assessed by considering whether technical problems were resolved appropriately.

Contextual factors

Data on contextual factors affecting recruitment and intervention delivery/fidelity were taken from meeting or researchers' field notes, and from email communications amongst the research team which included a research assistant, a project manager, and an IT person who helped manage the electronic recruitment database.

RESULTS

There were 1360 patients registered at the clinic immediately before the study began. A computer query of medical records run at this time to estimate the number of potentially eligible patients revealed that 802 (59.0%) fit the inclusion criteria listed in box 1. In total, 681 (50.1%) patients were invited to the study, 419 (30.8%) approached, and 86 (6.3%) enrolled. Figure 1 is an illustration of the contextual factors that reduced the number of potentially eligible patients to invite to the study, or/and prevented the research team from approaching patients previously invited. These factors are explained in more detail below.

Healthcare provider-related constraint: recruitment to another research study

Recruitment to another TH study led by a diabetes consultant at the diabetes clinic as part of The Health Foundation's SHINE programme to improve healthcare services (20) began during our study's recruitment period. The start of the Diabetes Appointments via Webcam in Newham (DAWN) project meant we were no longer authorized to recruit patients under the care of the lead consultant. This project included diabetes patients with an upcoming appointment who had a computer and Internet connection, and excluded new patients or patients for which an online consultation was not clinically appropriate (examination or diagnostics required). A query of our electronic recruitment database was run to establish the impact on our study's recruitment. Results indicated that 142 patients under the care of the lead consultant were potentially eligible for our study but had not been invited yet (at the time, this was an estimated 26% of the remaining potentially eligible patients to invite). There were also 58 patients under the lead consultants' care that were invited to our study, but that could no longer be approached.

Recruitment strategy constraint: reliance on in-person approach primarily

Our recruitment protocol relied primarily on in-person approach. This decision was related to the ethical requirement for a third-party clinical staff to make the initial contact with the patient about the study, the complexity of the study, and our preference to show patients the MTH equipment. Reliance on in-person recruitment approach meant that invitations were restricted to potentially eligible patients with an upcoming appointment. In total, 681 (50.1%) of the 1360 patients registered at the clinic were invited to the study during the 12 months (6 months longer than planned) recruitment period.

Institutional constraint: changes to the discharge criteria

At the time of recruitment, restructuration changes were ongoing as community health services in Newham were being integrated to the East London NHS Foundation Trust (21) and preparations to implement a new diabetes service model, the Newham Local Diabetes Enhanced Service, were beginning (22). To alleviate the busy diabetes clinic service, the discharge policy became more strict. Registered patients were discharged back to their GP after one non-attended appointment, unless they contacted the diabetes clinic following receipt of the discharge warning letter and within the timeframe required. A query of our electronic recruitment database (adjusted to pull information from the medical records on the discharge status) run at the time the discharge policy was changed indicated that 35 patients invited to our study had been discharged, and could therefore no longer be approached by the researcher. In addition, one participant enrolled on the study was sent a discharge warning letter. The research team contacted the participant to ensure they took appropriate action to remain registered at the clinic. As the computer query of medical records run to identify potentially eligible patients was updated to exclude discharged patients, the extent to which the change in discharge policy reduced the number of patients identified in subsequent queries is unknown. The high non-attendance rates in the area (see below) suggest however that this change is likely to have substantially reduced this number.

Practical constraints

In total there were 260 patients who were invited to the study, but not approached by a researcher. For 79 (30.4%) of these patients, this was due to manpower availability (the researcher responsible for recruitment was not always available to meet patients after their appointment), or difficulties in contacting patients over the phone (a minimum of 3 attempts were made) if they were not seen at their appointment by the researcher. In some rare cases, the patient was found to be deceased.

Patient-related constraint: non-attendance rates

Outpatient non-attendance rates were high in Newham, particularly for people from ethnic minorities who represented 64% of the Borough's population at the time (23). They were considered to be between 21-46% in the diabetes clinics at the time of recruitment (24). This did not work well with our recruitment strategy that required us to meet patients in person after their appointment. In total, 88 (33.8%) of the 260 patients who were not successfully approached by a researcher did not attend their scheduled appointment(s).

Exclusions

Of the 419 patients successfully approached by the researcher, 128 (30.5%) were found not to be eligible for the study. Table 1 describes the reasons for exclusions.

[Table 1 HERE]

Patient self-selection

Of the 291 patients approached and confirmed to be eligible, 205 (70.5%) refused to participate in the study (see Table 2 for reasons for refusal) and 86 (29.5%) were enrolled to the study. Calculated as the ratio of people who declined the invitation to take part on the study to the number of people whose eligibility was confirmed, the refusal rate in the current study was 70.5%. Further to this, 5 of the 86 participants did not return the baseline assessment, therefore in total 81 (94.2%) participants were randomized to a research group.

[Table 2 HERE]

Intervention delivery

A total of 358 contacts of any type (outgoing/incoming calls and text messages) occurred between MTH participants and the MTH team, with a mean of 8.95±3.31 and a range of 3-17. Below these data are broken down according to the purpose of contacts.

Technical support and device-related operations

As was reported in further detail in another paper (19), the engineer provided all (100%) MTH participants with at least one training session. There were 95 (26.5%) contacts between MTH participants and technical support, with a mean of 2.38±1.51 and a median of 2 (range 0-8). Table 3

describes these in further detail. The majority (75%) of MTH participants had fewer than 3 contacts with technical support. Twenty-six participants experienced a technical problem, and satisfaction with the quality of the technical support was reported to be good.

[**Table 2**. Contacts recorded on the web server between intervention participants (n=40) and the technical support team]

Clinical advice and feedback

There were 263 (73.5%) contacts between MTH nurses and participants, with a mean of 6.58±3.50, and a median of 6 (range 2-15). The majority (75%) of participants had fewer than 9 contacts with the MTH nurse, 25% of which had 4 or fewer. Table 4 gives additional information on these calls. Of the 92 calls initiated by the MTH nurse, 23 (25%) are likely to have been made to provide clinical advice and feedback on the data transmitted. Amongst the text messages sent by the MTH nurse, few were related to BG readings: 1.0% provided advice on BG control, 3.1% were comments on BG profiles, and 1.6% requested fasting BGs.

Patient education and other assistance

Thirty-two (34.8%) of the 92 calls initiated by the MTH nurse were to deliver education, and 37 (40.2%) were introductory calls. Text messages were the mode of contact the most frequently used (62.4% of all contacts by the MTH nurse). The most commonly sent text messages included thanking participants for transmitting data (24.4%), an introductory message at the start of the study (16.6%), Christmas wishes (16.1%), and encouragements to transmit data (8.3%).

[**Table 3.**Contacts between intervention participants (n=40) and the mobile telehealth (MTH) nurse]

Intervention fidelity

Intervention delivery data suggest that the technical and device-related aspects of the intervention were successfully delivered. All MTH training sessions were provided, and all technical problems resolved, with the exception of complaints about the battery life of the mobile-phones (n=3). Eight (20%) of the 40 end of trial calls required were not made. Web server notes indicated this was because of difficulties reaching participants (n=6) or non-use of the MTH equipment in the last two months of the trial (n=2).

In contrast, only 23 outgoing calls for clinical feedback were initiated by the MTH nurse. Because MTH clinical feedback was dependent on the value of clinical readings and clinical judgement, it was not feasible to verify whether the monitoring protocol (Baron et al., 2015) was followed appropriately. Given that MTH usage was relatively good (Baron et al., 2015) and that participants had poorly controlled diabetes however, it is likely they experienced hypoglycaemic or hyperglycaemic events during the study that required a greater number of clinical feedback calls than those recorded.

Data also showed that patient education and assistance was not likely to have been delivered appropriately. Three (7.5%) of 40 introductory calls were not completed. Web server notes however indicated that several unsuccessful attempts had been made. Thirty-two (13.3%) of the required 240 educational phone calls (6 required for each participant) were recorded as complete. The technical support team kept separate records of MTH contacts with participants (see legend in Table 2), however no such document was kept by the MTH nurse when asked. Data collected during a qualitative exploration of participants' experience using MTH (these will be reported in a separate paper) confirm the variability across participants in the amount of contacts with MTH nurses, and the lack of educational calls

Factors affecting intervention delivery

An important factor affecting the delivery of the MTH nurse-led components of the intervention, clinical feedback and patient education and assistance, were changes to the MTH nursing staff. As is shown in Figure 2, 3 MTH nurses were successively employed by the private MTH company to work on the study. The transition from the first to the second MTH nurse happened smoothly and efficiently over 3 days, but it took approximately 2.5 months (79 days out of the 488 days the study was open) for the third nurse to be recruited, during which no MTH intervention was delivered. Figure 2 indicates that MTH participants were affected differently by the staffing changes because they were recruited and commented onto the study at different time points. Sixteen participants were not affected by them. Remaining participants missed out on 1-3 months of intervention delivery, depending on the time at which they were recruited onto the trial. Other factors are likely to have affected intervention delivery, but these factors remain unknown.

[**Figure 2**. Timeline of changes to the mobile telehealth nursing staff during the quantitative study]

DISCUSSION

A first aim of this paper was to report detailed recruitment data from a MTH study. The data presented showed that participants enrolled represented only 6% of the 1360 patients with diabetes registered at the clinic, and 10.7% of the 802 identified as potentially eligible at the start of the study. Such detailed recruitment related data are not commonly reported in other MTH studies, perhaps because there is still a stronger emphasis in health research on internal validity than on external validity (25-27). Data from our study underlines the risk at which some MTH studies are to include a very select subsample of the intended population. Yet studies with a better balance between internal and external validity are likely to provide policy and decision-makers with higher quality evidence (26). Improved reporting of recruitment data can improve our understanding of the true therapeutic effect of the intervention, i.e. its 'real world' consequences (28), and can facilitate translation into practice (9).

A range of factors restricted access to research participants. First, the recruitment protocol decision to use primarily an in person approach was not ideal given patients' clinic attendance rates were low.

Other MTH studies have relied on multiple recruitment strategies (29). This may minimize the potential for contextual factors to affect recruitment outcomes, as well as increase the samples' representativeness. In particular, community-oriented strategies based on community partnerships, local events and church visits, have been effective with ethnic minorities (29;30). A second factor that reduced access to research participants was related to another trial recruiting participants, and the diabetes consultant restricting access to patients under her care. Researchers have reported that concurrent recruitment to other trials negatively affects recruitment (31), although this has usually been related to the additional work required from health providers. Gatekeeping in health care is common and includes some benefits for researchers (32). Interestingly, and as was the case in this study, the purpose of gatekeeping is not always consistent with patients' best interests. In fact, Sharkey and colleagues (33) believe that gatekeeping in clinical research is not ethically defensible because it does not respect patients' capacity for self-determination, and because it jeopardizes the merit of the research by introducing sample selection bias and decreasing accrual rates, resulting in an unfair distribution of the research burdens/benefits. To avoid the type of gatekeeping experienced in our study, researchers assessing the feasibility of their research at the design stage would benefit from enquiring about ongoing or upcoming research projects that might interfere with recruitment. Working towards developing eligibility criteria that do not overlap is likely to be mutually beneficial. Adding recruitment sites is an alternative method that can increase generalizability with appropriate selection (34). A third factor that affected the recruitment process to our study were changes to the discharge policy. Responses to Borschmann et al.'s (31) survey indicated there was a strong consensus amongst researchers that substantial organisational restructuring and changes to services inhibited access to research participants, although this was mainly seen to happen through demoralisation of clinical staff in reaction to job insecurity. It is difficult to pre-empt the effects restructuring and policy changes can have on research. Decisions are made at higher levels of authority (e.g. strategic health authorities, primary care trusts, and now more frequently by clinical commissioning groups). Ensuring clinicians are involved throughout study design and building solid professional partnerships with key stakeholders at research sites, are strategies that are likely to help minimize research disruption.

The factors that interfered with recruitment are likely to have introduced selection bias into the study. For example, clinic non-attendance has been related to higher HbA1c values (35). Potentially eligible patients not approached because of non-attendance, or discharged for the same reason, may have been more poorly controlled than those approached by a researcher. These selection effects are distinct to the bias resulting from patients' deciding for themselves whether to participate. Self-selection bias refers to the likelihood that this decision is based on reasons related to behaviours or attributes under study (36). Previous work suggests that people who accept to take part in health research may have better health outcomes compared to refusers (37). Although our response rate is lower than the 70% participation rate considered to be indicative of a representative sample (38), the refusal reasons provided in our study are similar to those provided in other research (39-43). The proportion of people (11.1%) who refused to take part because of a technology-related reason was

considerably lower than a recent telehealth study (44), which may be related to the distinction between mobile and fixed technologies.

In addition to the information self-selection can provide on sample representativeness, it is also important because it is an indication of what might happen if MTH was implemented in clinical practice in geographical areas with similar socio-demographics as the London Borough of Newham. Future MTH studies in areas with such characteristics may benefit from planning recruitment periods and methods accordingly. A culturally-sensitive recruitment process and intervention may be helpful. The suggestion for national standards for the provision of culturally and linguistically appropriate health care to include the provision of mobile health software in the preferred language of patients (45) is promising and could help maximize participation and retention.

A second aim of this paper was to report data on MTH intervention delivery and fidelity. The data collected showed that fidelity of delivery of the clinical feedback and education components was low compared to technical or device related operations. Importantly, MTH participants were affected differently MTH nurse staffing changes, adding complexity to the interpretation of the findings, and suggesting examination of the relationship between intervention delivery and health outcomes could be interesting. Several reviews have underlined the insufficient attention to the assessment of fidelity in interventional research, and the low fidelity in some studies (46-48). Our study reinforces the importance of monitoring intervention fidelity in MTH research, particularly in relation to clinical and educational interventions. The MTH service in this study was delivered by a private company with quality assurance controls of a confidential nature. Maintaining control over intervention procedures may have been facilitated if the MTH service was integrated to routine care and provided by the diabetes clinic clinical staff. Implementation frameworks such as the Normalization Process Model (49;50), evidence on the mechanisms most likely to ensure successful telehealth implementation (51), and previous work on organizational readiness for change in chronic care (52) can help inform which service delivery model is most appropriate to maximise sustainability.

The 2.5 months period during which no MTH nurse was appointed affected intervention delivery, but cannot alone explain the low number of clinical and educational feedback calls. Difficulties in contacting participants may have been a challenge and were anecdotally reported by the MTH team. The success of the technical support team and engineer to reach MTH participants when needed suggests however that this factor is unlikely to explain the low intervention fidelity. Another factor that may have influenced delivery is the training provided to the MTH nurses. The intervention protocol may not have been explained to them appropriately by the private MTH company. Interviews on, or observations of, provider training would have been useful and are recommended as part of fidelity assessments (53).

The data reported in this paper on recruitment and intervention delivery raises important questions on the external and internal validity of MTH studies. These data are not commonly reported despite their relevance in interpreting effectiveness findings. It is not uncommon for findings from initial RCTs to be contradicted or challenged over time as the intervention is tested in different

populations and settings (55). Achievement of good implementation appears to be related to larger effects (56). As such, recruitment and intervention delivery and fidelity may help explain the inconsistency of the findings on the clinical effectiveness of MTH across systematic. Their importance has been underlined in process evaluation frameworks(6), and their incorporation into future research agendas is likely to help achieve the potential of telehealth and support effective clinical and health policy decision-making. Finally, these issues are important in determining the scalability of telehealth systems. Further research on the generalizability of individual-level effectiveness would be beneficial to inform wider implementation of these services, and lessons learnt on intervention fidelity may be useful to support effective resource allocation and the quality of the delivery of care.

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AUTHORS' CONTRIBUTIONS

All authors were equally involved in the design of the study. JB was responsible for study implementation and data collection under the supervision of SN and SH. JB is the primary author of this paper, and revisions were made by SN and SH.

AUTHOR DISCLOSURE STATEMENT

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