Using mHealth for the management of hypertension in UK primary care

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ABSTRACT

Background: Self-monitoring of blood pressure is common but how telemonitoring (TM) with a mobile healthcare (mHealth) solution in the management of hypertension can be implemented by patients and health care professionals (HCPs) is currently unclear.

Aim: Evaluation of the facilitators and barriers to self-monitoring and (TM) interventions for hypertension within the TASMINH4 trial.

Design and Setting: Embedded process evaluation of Telemonitoring And Self-Monitoring in Hypertension (TASMINH4) randomised controlled trial (RCT), West Midlands, UK. Data analysed using Hamilton's Rapid Analysis Approach.

Methods: 40 participants comprising: 23 patients randomised to one of two arms, i) mHealth (self-monitoring by free text/SMS), ii) self-monitoring without mHealth (self-monitoring using paper-diaries), 15 HCPs and two patient caregivers.

Results: Four key priority areas relating to implementation of self-monitoring concerned i) acceptability of self-monitoring and telemonitoring to patients and HCPs ii) managing data iii) communication and iv) integrating self-monitoring in hypertension management (structured care). Structured home monitoring engaged and empowered patients to self-monitor regardless of the use of mHealth. Telemonitoring potentially facilitated more rapid communication between HCP and patients. Paper-based recording integrated into current work flows but required additional staff input.

Conclusion:

The convenience and ease of communication provided by telemonitoring was highly valued by all participants. However, the realities of current UK General Practice meant that a paper-based approach to self-monitoring could be integrated into existing workflows with greater ease. Self-monitoring should be offered to all hypertensive patients, with telemonitoring likely to gain traction as clinical systems evolve to better allow integration with external data sources.

How this fits in

- Self-monitoring of blood pressure is common but how telemonitoring can be implemented routinely by healthcare professionals and patients is currently unclear.
- This embedded process evaluation of the TASMINH4 trial highlights telemonitoring delivered by mobile phone was convenient and easy to implement in daily practice.
- Healthcare professionals and patients valued the ease of communication from telemonitoring, and the automated calculation of average BP but found that paper-based recording integrated better with current workflows in UK general practice.
- Telemonitoring using an mHealth solution is a promising tool and should be offered for supporting hypertension self-management alongside traditional paper-based recording.

BACKGROUND

Mobile healthcare (mHealth), defined as the use of mobile and wireless technologies for health,[1] has the potential to improve access to and use of health services. Digital health interventions that can be delivered by mobile phone offer scalable, potentially cost-effective ways to improve medication taking behaviours and include promising tools for supporting hypertension self-management.[2]

Hypertension or high blood pressure (BP)[3] is the most significant risk factor globally for cardiovascular diseases (CVD) such as heart attack or stroke and lowering BP reduces these outcomes.[4-7] In England, approximately 30% of adult men and women have hypertension, with little recent change in prevalence, but many remain uncontrolled.[8] Self-monitoring, with or without additional support such as provision of educational materials, tele-counselling or telemonitoring (electronic transmission of BP data), has been shown to lower BP, with greater intensity of co-intervention associated with greater effect on BP.[9] Evidence for the use of BP self-monitoring values by GPs to titrate antihypertensive medication in primary care, has until recently been equivocal [10, 11] but this has changed with the Telemonitoring and Self-management in Hypertension Trial (TASMINH4).[12]

TASMINH4, a national randomised controlled trial (RCT) in 138 General Practices was designed to evaluate clinician antihypertensive titration using self-monitored BP values either sent to clinicians by free short message service (telemonitoring) or manually posted to surgeries via paper diaries (self-monitoring alone). After one year, those in both self-monitoring groups had significantly lower systolic BP than those whose medication was adjusted using clinic readings.[12] The telemonitoring group had more rapid BP reductions and both groups were prescribed more antihypertensive medication. No significant changes were detected in adherence to antihypertensive medication or to lifestyle factors.

We carried out an evaluation of the trial processes to understand how the self-monitoring interventions used in TASMINH4 for BP management were implemented by patients and health care professionals (HCPs) to identify any facilitators and barriers promoting or inhibiting implementation.

METHODS

Participants

The study population for this qualitative study included patients, their caregiver (defined as a spouse/friend/relative who identified themselves as helping patients with any aspect of hypertension management) and health care professionals (HCPs, employed in practices based in the West Midlands) taking part in the TASMINH4 RCT [ISRCTN 83571366, registered 17 July 2014].[13] The TASMINH4 trial commenced in November 2014 and phased recruitment of patients to the present qualitative study commenced between March 2015 and Sept 2016. Patients aged over 35 with clinic BP not controlled below 140/90 mmHg were eligible for this process evaluation.[12] Patients not agreeing to participate were excluded. For practical reasons, all interviews were conducted in central England.

Study Processes

We consulted established criteria in the reporting of the present qualitative study.[14] Full details of the TASMINH4 interventions have been published previously.[12, 13] In brief, participants were randomised to intervention and control (usual care) groups.

Intervention Groups comprised:

I. Self-monitoring alone (self-monitoring plus recording readings on paper diaries and posting these to the practice)
II. Self-monitoring with telemonitoring (self-monitoring plus telemonitoring [sending readings via a SMS text based telemonitoring service with web-based data entry back up – mHealth solution] Figure 1)

<Insert Figure 1>

Following randomisation, all participants were asked to attend their own GP for a medication review. GPs used self-monitored BP to titrate antihypertensive medication in both self-monitoring groups. Participants randomised to usual care were managed with titration of antihypertensive treatment based on clinic BP measurements at the discretion of their attending HCP. (Box 1) Participants randomised to the self-monitoring interventions, self-monitored BP for twelve months.

<Insert Box 1>

Sampling Strategy

Recruitment of participants were from a convenience sample of 2 areas, Birmingham and the Black Country (BBC) and West Midlands South (WMS), both regions within central England. This area was chosen because together they cover a diverse range of patients in terms of levels of social deprivation and urban/rural diversity. Participants were purposefully sampled[15] to reflect a range of deprivation levels [16] and to ensure a range of views based on gender, participant (HCP or patient) and randomisation arm. Usual care participants were interviewed to add further context; however, because the present paper focuses on understanding the implementation of the self-monitoring interventions in management of hypertension their views are not reported here. Caregivers identified as assisting with self-monitoring were consented and interviewed separately in their homes. HCPs were interviewed at their respective practices. The flow of trial participants is outlined in Suppl 1.

Design and data collection

Interviews occurred between November 2015 and September 2016, parallel to trial data collection, recruiting participants after a minimum of six months of trial experience. They were conducted by multiple researchers (SGra, JH, PB, SM, LH, AT, CS) whose background and disciplines included health psychology, sociology and nursing. Structured topic guides modified to suit each intervention arm were used, informed by a previous self-management study[17] (Suppl 2-4). Each interview lasted approximately one hour, was audio-recorded and transcribed verbatim. Recruitment continued until data saturation for implementation themes was reached within patient and HCP groups separately.[18] In line with our analysis approach below, we sought perspectives from three key informants involved directly in the trial (i.e. patients, their carers, and HCPs).

Data Analysis

Hamilton's rapid analysis approach[19] was used to understand how patients and HCPs adopted the interventions. This is a 'tailored approach' of an application of information and strategies for rapid cycle projects from the Rapid Assessment Process pioneered by John Beebe in 2001. This approach has been used in many different fields by many different individuals. Whilst the TASMINH4 trial was not in itself a rapid project, qualitative interviews were conducted alongside the trial and analysis of the incoming data was required to be assessed rapidly as part of the process evaluation. Assessment of the data through team based qualitative enquiry involving multiple researchers in data collection and analysis enables intensive triangulated qualitative inquiry to iteratively provide understanding from the 'insider's' perspective.[19, 20] Distinct from other conventional approaches, this form of qualitative inquiry and methods is designed to give a preliminary understanding of key themes arising out of the data designed for situations where information is needed within a short timeframe (e.g. to inform a trial or where service change needs to be implemented quickly), rather than a more in-depth understanding. Importantly it uses methods which give a systematic approach to doing so. [19] Figure 2 outlines the processes involved in the rapid analysis using templates (Suppl 5) developed by the researchers [SGra, JH, PB, SGre] based on the topic guides' contents and derived for healthcare professionals and patients separately. These templates were subsequently

refined after a period of 'road testing'[19] and the domains were reclassified through a number of phases to yield the four key areas described below.

<Insert Figure 2>

RESULTS

15 of the 18 practices selected, agreed to participate. Of the 59 trial patients listed within these 15 practices, 39 were approached, six did not respond, and three declined to participate resulting in 47 interviewed participants (30 patients [including 7 usual care], 2 caregivers, 15 HPs). Characteristics of the study population and participating practices are detailed in Table 1.

Four key priority areas emerged that relate to how the interventions were applied within participating practices. The facilitators and barriers to self-monitoring and telemonitoring are summarised in Table 2 classified by priority area.

Acceptability of self-monitoring/ telemonitoring to patients and professionals

Regular home monitoring was preferred by patients to visiting the GP surgery for BP measurement. Irrespective of the self-monitoring arm randomised into, patients felt "looked after" and found either method of communicating self-measured BP manageable. (Table 2) Patients who telemonitored described the process as a 'slick operation' whilst HCPs found the data provided electronically as "brilliant" for accessing quickly a monthly view of readings, and the graphing "awesome" in contrast to dealing with the paper-based records, which one GP described as "unwieldy".(Table 2) Amongst the telemonitoring group, patients liked being able to use their own mobile phone for sending BP readings electronically resulting in wider acceptance of the intervention amongst the more technophobe participants. Similarly, HCPs favoured the rapid and direct mHealth solution for reviewing patients' BP readings, over what they felt was the more time-consuming process of calculating means from the paper record. Patients and HCPs recognised that telemonitoring may not be a suitable way of sending readings for all patients, such as the more elderly, and so felt a conventional paper record option was an important alternative. (Table 2 and 3)

Managing data

Each practice had autonomy regarding their management of patients and how self-monitoring was implemented within their organisation. The trial specified that patients undertook self-monitoring following a standard schedule and posted or sent readings electronically. (Box 1) For manual recordings, GPs nominated a member of staff, usually the practice nurse or manager to handle the paperwork, calculate monthly BPs and enter this on to the practice clinical system for GP review. Whilst the paper based records integrated better within existing clinical systems via scanning documentation, HCPs favoured the rapid and direct mHealth solution over what they felt was the more time-consuming paper record. Both self-monitoring interventions however ultimately required human effort to input the average monthly BP into the clinical system, which could have increased the likelihood of human error.

HCPs set up personal reminder systems to review patients' readings but, in some cases, where the designated nominated staff member was not present, GPs would have to deal with the paperwork personally.(Table 2) Although HCPs had to spend extra time logging into a separate web portal, the automatic calculation of average BP by the system meant GPs generally favoured telemonitoring over the manual written log. Data confidentiality, security and the potential risk of important medical advice being received by the wrong person or easily missed were among concerns raised by some GPs over telemonitoring. (Table 3)

Communication

A key aspect of the interventions within TASMINH4 was for HCPs to manage and titrate medication using self-monitored BP. Medication changes were recalled for patients in the telemonitoring arm only. For those requiring a change, and where BP values were seen out of normal range on the system prompted the GP to initiate contact. They felt this improved communication around BP resulting in more rapid control (Table 2 and 3). For the few GPs using the text-back facility some felt complete advice was not always possible within one text and there was a need to safeguard confidentiality by keeping communication non-committal so, in such cases, face to face follow up appointments were sometimes felt necessary. Irrespective of the method by which patients sent in readings (whether post or

text) patients felt empowered from engaging in their own BP monitoring. Those within the telemonitoring arm valued timely interaction with the system (and by extension their GP) and whilst text acknowledgement messages were automated when patients sent readings, they were nevertheless reassured from this instant feedback.

Integrating self-monitoring in hypertension management (structured care)

HCPs and patients adapted integration of self-monitoring into their BP management and this was illustrated within the telemonitoring arm. If patients could not use their existing mobile phone, though the study supplied patients with a phone, they borrowed a mobile phone or asked their partner or caregiver to send the SMS message. Patients and HCPs found both self-monitoring systems and schedules easy to use. Minor technical problems experienced with the mHealth system were alleviated after brief consultation with the study research team. Conventionally GPs would undertake annual reviews of hypertensive patients, but both self-monitoring interventions enabled more intense monitoring and follow up with intervention where needed or reassurance where not. Clinicians felt any decisions about medication changes for patients telemonitoring were based on a reliable database of BP readings. (Table 2 and 3)

<Insert Table 2>

<Insert Table 3>

Discussion

Summary

The present qualitative process evaluation aimed to evaluate the facilitators and barriers to self-monitoring and telemonitoring within the TASMINH4 trial. HCPs managed patients' medications based on self-monitored readings as they would routinely, regardless of the mode of transfer.

Telemonitoring of BP was convenient and therefore acceptable to most patients and HCPs with a notablyfew stating it was time consuming. Telemonitored data facilitated regular communication between clinicians and patients relating to BP and supported rapid clinical

decisions about intensifying medication for patients. The paper-based option however integrated better with practice records offering a simple scan and storage process, directly matching the readings to the patient within the GP practice's clinical system. Integration has previously been documented as a requirement for accepting telehealth systems in the long term.[21, 22] Patients and HCPs agreed that telemonitoring may not suit all people across a wider population. The benefits of structured care provided by both self-monitoring methods over standard clinical BP management were perhaps as important as the method of monitoring communication.

Some concerns were raised over data confidentiality by clinicians as previously reported with mobile data usage;[23] these concerns could be reduced by limiting the advice given within the character allowance of one SMS and booking an additional face to face appointment in the event a medication change was needed, but clear advice to this effect would be necessary. This may reduce the potential savings in time associated with telemonitoring.

Strengths and limitations

This study was embedded within a large RCT[24] with flexibility regarding the implementation of mHealth within practices, avoiding the need for HCPs to adhere to strict protocols. Qualitative approaches are ideal for exploring the mechanisms of adoption of such interventions and therefore important in maximising future dissemination.[25]

Rapid analysis[19] is designed to enable a prompt preliminary understanding of key priority areas and key features of interventions when considering implementation in wider practice.[19, 26] We therefore ensured a range of expertise within our team of researchers who were also responsible for the data analysis to facilitate this rapid process evaluation. The present analysis provides suggestions of the key areas relating to implementation to focus a deeper inductive analysis in the future by other researchers.[20, 26]

Whilst purposive sampling was carried out in the present study with equal representation of men and women across the HCP and patient population, like the TASMINH4 national RCT there was under representation of non-white ethnic minorities across the sample. Our

findings and conclusions could be different if other medical practices had participated in the trial.

Comparison with existing literature

These findings are contrary to previous research investigating the use of self-management mHealth technology: a Swedish study [27] of a mobile phone-base support system or platform and an Irish study by Morrison et al [28] of a smartphone application found participants expressed difficulty using the mobile platforms. Patients telemonitoring in the present study did not report such difficulties suggesting an advantage of using SMS (texts) enabling compatibility with patients' existing environments and ease of delivering BP readings, key elements of telehealth interventions that ensure successful implementation.[29] Furthermore, our recommendation of the availability of an equally cost-effective[30] paper-based method of recording and sending readings is an additional way to facilitate wider appeal. In a recent meta-ethnography of digital health interventions across wider health conditions, Morton et al [31] conclude engagement with such tools provides reassurance from the insight patients receive into their health. This is both motivating and empowering for patients, supporting the findings of the present study and the conclusions of other studies relating specifically to hypertensive populations.[32, 33]

Effective communication between hypertensive patients and GPs has been emphasised across several previous studies [34] and was identified as a key priority area for implementation. The mobile texting system potentially enabled opportunity for discussion via consultation concordant with findings by Hallberg et al[27] and two recent systematic reviews that technology-based strategies that prompt and promote user engagement are more likely to be effective.[35, 36]

Implications for clinical practice

The present study suggests self-monitoring, whether it is using a mobile text-based system or a diary paper-based record, is relatively simple, cost effective[30] and potentially easy to adopt for managing hypertension in Primary Care. A system whereby HCPs can be easily alerted to patients in whom intensification of anti-hypertensive BP medication is necessary appears favourable over conventional paper-diary methods although the latter is

recommended as a required alternative option to suit the broader population. Overall, a system easily accessed by patients using their existing non-smartphone mobile phones makes this an acceptable form of telemonitoring.

Declarations

Ethics approval and consent to participate: Ethical Approval was given on 07/07/2015 by NRes Committee, South Central Oxford B, Ref 14/SC/0218, AM02 05/06/2015

Consent for publication: Not applicable

Availability of data and material: The full data set is not publicly available for reasons of confidentiality.

Competing Interests: None

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Authors' contributions - All authors contributed to the conception of the study. SGra developed the first draft of the manuscript. SGra, JH, PB, CS contributed to data collection. SGre, JH, PB, CS, RM contributed to data analysis and provided methodological input. All authors read and edited several versions of the manuscript. All authors read and approved the final manuscript.

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Tables, figures and supplementary files

Table 1 – Summary of participants' characteristics

Table 2 – Facilitators and barriers to self-monitoring and telemonitoring interventions, classified by key implementation priority area

Table 3 – Participant quotations

Box 1 – Participant training and Intervention Description

Figure Legends

Figure 1 - System architecture

Figure 2 - Flow diagram of the rapid analysis approach

Supplementary Files

Suppl 1: Patient flow through study

Suppl 2-4: Topic guides – just the topic guide

Suppl 5 – Hamilton's rapid analysis template proformas (HCP and Patient)