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## What influences withdrawal because of rejection of telehealth – the whole systems demonstrator evaluation

Lorna Rixon, Shashivadan P. Hirani, Martin Cartwright, Michelle Beynon, Abi Selva, Caroline Sanders and Stanton P. Newman

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### Abstract

**Purpose** – *The widespread deployment of telehealth (TH) has been conducted in the absence of any clear understanding of how acceptable these devices are to patients. One potential limitation of the widespread deployment of TH is that patients may refuse. Moreover an understanding of the reasons for refusing to use TH devices will provide an understanding of the barriers.*

**Design/methodology/approach** – *This investigation from the Whole Systems Demonstrator (WSD) programme, a pragmatic cluster randomised controlled trial into the effectiveness of TH, examined reasons for patients in the intervention cohort of the trial refusing TH, and the potential barriers to its deployment.*

**Findings** – *Active rejection of the TH intervention was the most frequent reason for withdrawal. After examination of trial-related, health, socio-demographic, cognitive, emotional and behavioural factors, patients diagnosed with diabetes, as opposed to heart failure or chronic obstructive pulmonary disease, and patients' beliefs about the acceptability of the intervention predicted whether or not they withdrew from the trial because of the intervention.*

**Originality/value** – *Beliefs that the TH intervention resulted in increased accessibility to care, satisfaction with equipment and fewer concerns about the privacy, safety and discomfort associated with using TH equipment predicted continued participation in the WSD trial. Findings suggest that potentially modifiable beliefs about TH predict those more likely to reject the intervention. These findings have important implications for understanding individual differences in the acceptance of TH and subsequent success in mainstreaming TH in healthcare services.*

**Keywords** *Telehealth, Acceptability, Dropout, Refusal of TH*

**Paper type** *Research paper*

### Introduction

Assistive technologies are increasingly being researched and deployed in healthcare settings with the ideal of benefits to both patient outcomes as well as a reduction in cost to the service provider. Telehealth (TH) technologies refer to assistive technologies that allow for the remote exchange of data between a patient in their home and healthcare professionals, in order to assist in the monitoring and management of long-term health conditions such as diabetes, heart failure and chronic obstructive pulmonary disease (COPD). However, studies investigating potential benefits of TH have reported some difficulty in recruitment prior to any experience with TH services, with refusals as substantial as 80 per cent (Mair *et al.*, 2006). In addition to socio-demographic factors such as lower academic attainment (Krousel-Wood *et al.*, 2001), older age, poorer health status and rural locality (Mair *et al.*, 2006; Palmas *et al.*, 2006; Van Beijsterveldt *et al.*, 2002; Radler and Ryff, 2010), reasons given for refusal include beliefs that the technology would not be of benefit, or would add nothing to the care they already

receive (Subramanian *et al.*, 2004). A qualitative study within the Whole System Demonstrator (WSD) programme, reported three key reservations expressed by patients and carers for non-participation: interventions could undermine self-care, independence and sense of identity; concerns about technical competence to use equipment; and expectations that interventions would disrupt existing services (Sanders *et al.*, 2012).

However, little is known about why patients reject TH after they have had some experience of using it. To understand why this occurs the objective of the current quantitative study was to examine factors associated with subsequent rejection of TH services by participants within the WSD programme, who initially accept installation of TH, then decide to withdraw from the study because they no longer wished to use TH.

## Methods

### *Trial design and participants*

Data were collected as part of the WSD programme, a pragmatic cluster randomised control trial, the full details of which have been reported elsewhere (Bower *et al.*, 2011). The present study reports on the intervention cohort of the trial. The study setting was conducted in England at three WSD sites: Cornwall, Kent and Newham, all primary care trusts and local authorities in these WSD Sites participated in the trial. The trial was designed to evaluate the provision of TH for patients with COPD, diabetes and heart failure. The current investigation examined withdrawal in the TH group through rejection of the TH intervention. Analyses presented here examine attrition from the trial due to not wanting TH after completion of the baseline assessment and short-term follow-up questionnaire assessment.

The study was approved by the Liverpool Research Ethics Committee (Ref: 08/H1005/4) as is customary in the UK applicants for multisite ethics approval access a committees with specific expertise in the programme of research and who can provide timely access for review. Written consent was obtained from all participants. The general practitioner practice was used as the unit of randomisation in this pragmatic cluster randomised controlled trial. GPs were randomised by the trial statistician balancing for region, practice size, deprivation index, proportion of white patients and prevalence of COPD, diabetes and heart failure. All eligible patients under the care of each general practice were allocated to standard care or TH.

### *Intervention*

The study was designed to examine a range of TH devices, each allowing the transmission between biometric data between patients and staff in the local monitoring centres. Participants had peripheral monitoring devices installed appropriate to their condition. According to protocol, participants with diabetes received a glucometer, participants with COPD received at least a pulse oximeter and weighing scales and participants with heart failure received at least a blood pressure monitor and weighing scales. The frequency of submitting clinical readings to the monitoring centres were individually tailored depending on the patient's clinical condition and care requirements. Clinical readings were classified by automated algorithms, which triggered a range of responses at the monitoring centre including conservative management, requesting a repeat reading, contacting the participant, or referral for additional planned, or emergency medical intervention (Cartwright *et al.*, 2013). The TH intervention lasted 12-months unless participants decided not to continue (e.g. refused to continue with the intervention) or could no longer continue (e.g. passed away, or became too ill to continue with the trial) and withdrew from subsequent participation.

### *Procedure*

All patients diagnosed with at least one of the long-term conditions COPD, diabetes or heart failure, and gave informed consent were entered into the trial. Patients who were participating in the trial were invited to participate in the nested questionnaire study. Willing participants were contacted by trained interviewers and a baseline interview arranged in the participant's home at which point written consent was obtained. Demographic and clinical details were recorded. Questionnaires were administered by the evaluation team (see Box 1) between May 2008 and

December 2009, and short-term follow-up questionnaires were posted three to four months later, as appropriate, which included the Service User Technology Acceptability Questionnaire SUTAQ. Withdrawals and the reasons for withdrawal using standardised withdrawal codes (see Table I) were recorded.

Box 1: Questionnaire assessments included in the analysis		
Questionnaire	Measures	Score meaning
Short Form SF-12 (SF-12) (Jenkinson and Layte, 1997)	Quality of life: Physical component score (PCS) Mental component score (MCS)	Higher score indicates better quality of life
Brief State Trait Anxiety Inventory (STAI) (Marteau and H, 1992)	State Anxiety	Higher score indicated greater anxiety
Centre for Epidemiologic Studies Depression Scales (CESD -10) (Andresen <i>et al.</i> , 1994)	Depression	Higher score indicates greater depression
Generalised self-efficacy scale (GSES) (Schwarzer and Jerusalem, 1995)	Confidence in ability to perform a behaviour	Higher score indicates greater perceived personal control
Health Education Impact Questionnaire (heiQ) (Osborne <i>et al.</i> , 2007)	Potential self-management capabilities: Skill & Technique Acquisition Constructive Attitudes & Approaches Self-Monitoring & Insight Health Services Navigation Social Integration & Support	Higher score indicates greater capability
Self-care behaviour and self-efficacy of self-care behaviour (developed by the WSD Evaluation team)	Self-care behaviour and self-efficacy of these behaviours: Followed a healthy diet Followed the level of physical activity recommended Adjust daily life to cope with health Able to monitor the symptoms etc Successfully been able to manage health in order to do things I enjoy Utilised health-care to support management of health	Higher score indicates better self-care behaviours and greater self-efficacy in performing these behaviours
Service User Technology Acceptability Questionnaire (SUTAQ) (developed by the WSD Evaluation team) (Administered at short-term assessment after experience)	Acceptability: Enhanced care Increased accessibility Privacy & discomfort scale Care personnel concerns Kit as substitution Satisfaction	Higher score indicates perception that TH enhances care, increases accessibility, greater privacy and comfort, greater personnel concerns, perception of kit as a substitution, and greater satisfaction.

**Table I** Withdrawal after baseline from the telehealth questionnaire study comparison of Telehealth (TH) to the control group

Withdrawal reason	TH Questionnaire study, n (%) / 845	Control group comparison of TH Questionnaire study, n (%) / 728
Rejected telehealth (TH); no longer wishes to be in the intervention group and rejects the equipment after trying for a period	107 (12.66%)	na
No longer wishes to be in the control group	na	26 (3.57%)
No longer wishes to share data	5 (0.59%)	1 (0.14%)
No longer wishes to participate as questionnaire is too onerous	4 (0.47%)	4 (0.55%)
Moved out of area to non-participating GP practice	12 (1.42%)	7 (0.96)
Absence from home or loss of contact	5 (0.59%)	2 (0.27%)
Problem with equipment (e.g. equipment broken, no longer working, misused)	5 (0.59%)	2 (0.27%)
Deceased	47 (5.56%)	48 (6.59%)
Physical or mental illness	22 (2.25%)	30 (1.91%)
Residential or nursing care	3 (0.36%)	10 (0.64%)
No reason given	5 (0.59%)	0

## **Statistical methodology**

The findings were analysed in two parts. First, a comparison between those who withdrew at any stage after receiving the TH intervention compared to those who completed the trial in the TH group. Second, an analysis of those who completed the short-term assessment, which compared those who withdrew and those who completed. The latter comparison was performed as at the short-term assessment. Participants withdrawing for all other reasons were excluded from the analysis. A questionnaire formally assessed attitudes towards the TH intervention (see Box 1 for Questionnaire assessments).

For each set, initial series of univariate logistic regression analyses were conducted, with each predicting rejection of the TH intervention. Predictors included: socio-demographic and trial-related variables – deprivation, age, gender, ethnicity, number of co-morbidities, the number of peripheral devices, the type of long-term condition (COPD, diabetes or heart failure), participants' academic attainment and marital status; baseline patient reported questionnaire scores: quality of life (SF-12), anxiety (STAI), depression (CESD-10), health education needs or level (heiQ), self-care and self-efficacy of self-care; and for the sample that completed a short-term follow-up (approximately four months) TH intervention acceptability beliefs (SUTAQ).

Variables significant ( $p < 0.05$ ) at predicting rejection of kit were entered into multivariate backwards entry binary logistic regression. Assumption testing was through examining: standardised residuals (required to be  $< 3.00$ ), leverage ( $< 1.00$ ), Cook's distance ( $< 1.00$ ) and variable inflation factors (co-linearity  $< 10$ ). The models were evaluated by the significance of  $\chi^2$  ( $p < 0.05$ ), percentage of cases correctly classified and Nagelkerke's  $R^2$ .

## **Results**

The most frequent reason for withdrawing from the TH study was because the participant actively chose to no longer be in the intervention group and rejected the equipment after trying for a period of time (see Table I).

### ***Comparison between those who withdrew at any stage and those who completed in the TH arm of the trial***

*Predictors of rejecting TH at any stage of the trial.* Predictors of rejecting the TH intervention were examined in the 107 participants who chose to withdraw because of the TH intervention vs the 632 participants in the TH group who completed the trial (see Table II). Rejection was higher in participants with diabetes, those who had more pieces of TH equipment, with poorer health services navigation skills, and lower confidence in ability to utilise the healthcare system to manage health, and lower academic attainment (see Table III). The overall model was significant with Nagelkerke's  $R^2 = 0.061$ ,  $\chi^2 = 22.661$ ,  $p < 0.001$ , sensitivity = 0, specificity = 99.84, overall accuracy = 86 per cent, although it only explained a small amount of variance.

### ***Comparison between those who completed the short-term assessment and did or did not retain the TH kit for the duration of the trial***

Predictors of rejecting the TH intervention were examined in the 30 participants who chose to withdraw because of the TH intervention and completed the short-term follow-up questionnaires vs the 409 participants retaining the TH and completing the trial (including short-term questionnaires). Table IV indicates that patients with diabetes, a perception that the intervention did not increase access to healthcare, invaded privacy and increased discomfort, and had lower satisfaction were at greater risk of rejecting TH. The model for risk factors predictive of TH rejection after short-term follow up resulted in a better model than above, Nagelkerke's  $R^2 = 0.245$ ,  $\chi^2 = 44.519$ ,  $p < 0.001$ , sensitivity = 3.57, specificity = 99.51, overall accuracy = 93 per cent.

## **Discussion**

Much previous research on refusal of TH has examined refusal to participate or accept TH, which is based on a perception of what a TH service would be like. This study examined people

**Table II** Sample characteristics of those who completed the assessment and those who rejected TH after baseline and short term follow up excluding those who withdrew for other reasons

	Baseline analysis		Analysis following short-term assessment	
	Completed (n = 632) Rates (expected)/mean (SD)	Rejected TH (n = 107) Rates (expected)/mean (SD)	Completed (n = 409) Rates (expected)/mean (SD)	Rejected TH later after short-term follow up (n = 30) Rates (expected)/mean (SD)
<i>Socio-demographic and trial related factors</i>				
Female	545(546)	93(92)	158(158)	12(12)
Male	87(86)	14(15)	251(251)	18(18)
Age	69.61	71.51 (15.40)	70.68(9.77)	70.11(12.94)
Deprivation	26.72	29.37 (18.59)	23.97(13.36)	25.24(15.65)
Number of chronic conditions	1.78	1.84 (1.93)	1.67(1.74)	1.60(1.79)
Ethnicity – white British	571(546)	93(92)	380(378)	26(28)
Non-white British	87(86)	14(15)	29(31)	4(2)
COPD	255(248)	35(42)	188(184)	9(13)
Diabetes	168(180)	43(31)	79(84)	11(6)
Heart failure	209(204)	29(34)	142(142)	10(10)
Amount of TH kit	2.75	2.93 (0.71)	2.70(0.59)	2.80(0.71)
<i>Patient Reported Measures</i>				
SF12 physical component	31.57	30.92(10.68)	32.36(9.03)	32.36(10.14)
SF12 mental component	36.80	35.81(9.11)	37.50(7.88)	38.09(8.77)
Skill and technique acquisition (heiQ)	4.58	4.49(0.77)	4.68(0.77)	4.64(0.80)
Constructive attitudes and approaches (heiQ)	4.61	4.53(1.07)	4.72(0.99)	4.59(1.13)
Self-monitoring and insight (heiQ)	4.87	4.74(0.65)	4.93(0.62)	4.84(0.74)
Health services navigation (heiQ)	5.01	4.84(0.87)	5.05(0.80)	4.82(1.00)
Social integration and support (heiQ)	4.70	4.54(1.01)	4.75(0.97)	4.48(1.18)
Generalised self-efficacy	3.07	3.02(0.61)	3.11(0.54)	3.07(0.63)
State anxiety	1.67	1.83(0.76)	1.59(0.60)	1.66(0.73)
Depression	0.97	1.06(0.64)	0.90(0.56)	0.99(0.74)
Followed a healthy diet	4.13	4.32(1.49)	4.27(1.50)	4.00(1.56)
Followed the level of physical activity recommended	3.63	3.41(1.78)	3.69(1.74)	3.21(1.87)
Adjust daily life to cope with health	4.06	4.03(1.77)	4.11(1.66)	4.55(1.57)
Able to monitor the symptoms, etc.	4.32	4.49(1.26)	4.49(1.42)	4.86(1.38)
Successfully been able to manage health in order to do things I enjoy	4.07	4.07(1.48)	4.22(1.44)	3.90(1.74)
Utilised health-care to support management of health	4.24	4.42(1.31)	4.37(1.57)	4.17(1.67)
Confidence in ability to follow a healthy diet	4.56	4.33(1.55)	4.72(1.35)	4.41(1.72)
Confidence in ability to follow level of physical activity recommended	3.63	3.46(1.86)	3.67(1.79)	3.72(2.02)
Confidence in ability to adjust daily life to cope with health	4.61	4.43(1.45)	4.73(1.25)	4.72(1.39)
Confidence in ability to monitor symptoms etc	4.86	4.74(1.29)	4.97(1.15)	5.07(1.25)
Confidence in ability to successfully manage health in order to enjoy things	4.38	4.26(1.42)	4.55(1.31)	4.55(1.38)
Confidence in ability to utilise the health-care system to management health	4.97	4.57(1.41)	5.07(1.11)	4.79(1.63)
Academic attainment	0.87	0.36(0.83)	0.93(1.24)	0.93(1.44)

asking for TH to be removed after some experience. It is of note that rejection of the TH intervention was the most frequent reason given for withdrawal from the WSD trial accounting for slightly over 12 per cent of participants in the intervention group. This suggests that after experience of a TH service, allowing for an informed and active judgement, a proportion of participants perceived no added value in continuing to use the TH service. At best they perceived no discernible benefit, at worst; they may have found it disruptive.

The multivariate analysis examined whether there were any predictors of rejecting the TH intervention at any time after the baseline assessments. Two of the four significant factors, lower academic attainment and having diabetes, have been reported as reasons to refuse to accept



**Table III** Multivariate logistic regression: baseline predictors of rejecting TH

	<i>B (SE)</i>	<i>Sig.</i>	<i>Change in odds exp (β)</i>	<i>Lower CI</i>	<i>Upper CI</i>
Diabetes	0.521 (0.223)	0.019	1.683	1.088	2.603
Amount of TH kit	0.322 (0.164)	0.049	1.379	1.002	1.899
Confidence in ability to utilise the health-care system to management health	-0.180 (0.079)	0.022	0.835	0.716	0.975
Academic Attainment	-0.263 (0.109)	0.016	0.769	0.621	0.953

**Table IV** Multivariate logistic regression: baseline and short-term predictors of rejecting the TH intervention

<i>Rejection of TH intervention</i>	<i>B (SE)</i>	<i>Sig.</i>	<i>Change in Odds Exp (β)</i>	<i>Lower CI</i>	<i>Upper CI</i>
Diabetes	1.059 (0.451)	0.019	2.885	1.192	6.981
SUTAK: increased accessibility	-0.572 (0.162)	0.000	0.564	0.410	0.776
SUTAK: privacy and discomfort scale	0.390 (0.197)	0.047	1.478	1.005	2.172
SUTAK: satisfaction	-0.406 (0.199)	0.042	0.666	0.451	0.985

TH prior to experience. These findings are similar to the findings of other research on telemedicine for patients with hypertension, where lower educational attainment was predictive of a higher rejection rate compared to other socio-demographic variables, such as, gender, age and ethnicity (Palmas *et al.*, 2006). Although there is no evidence base to quantify and examine factors associated with patients' decisions to reject TH following the recruitment phase, research from other disciplines indicate that individual's with lower academic attainment are also more likely to decide to dropout compared to those with a higher educational attainment (Radler and Ryff, 2010; Van Beijsterveldt *et al.*, 2002). This suggest that patients with lower educational attainment are not only at risk from poorer recruitment rates, but are also at greater risk of deciding not to continue after having the equipment installed in their homes.

The presence of diabetes as a factor leading to greater rejection of TH may reflect that most people with diabetes are well practiced in recording their clinical data. It is possible that the introduction of a new system to do this may have been perceived as a disruption to a well-practiced regime in comparison to those with COPD or CHF. This may have resulted in patients with diabetes finding TH less acceptable. Although patients with diabetes may have different socio-demographic characteristics and quality of life compared to patients with COPD and heart failure, the presence of diabetes was a more robust predictor than other potential explanatory factors such as educational attainment, age, gender and a range of patient reported outcomes which were not found to be significant. There are a number of other possible explanations for the finding as to why those with diabetes were more likely to reject TH and whether this would be evident in other studies and this warrants further investigation.

Participants with a greater number of peripheral devices and lower confidence in being able to navigate the healthcare system were also at greater risk of withdrawal from TH at any time after baseline. Both these factors may reflect the difficulties in dealing with complexity and indicate potential areas for further tailoring of interventions. The increased number of devices may increase complexity for the participants and withdrawal was associated with individuals who found the healthcare system difficult to navigate. The disruptive impact of complex requirements can increase the burden of work for users of these interventions and can be viewed to be a major barrier to the adoption of new interventions (May *et al.*, 2009; Oudshoorn, 2008).

The analysis of the participants who completed their four month follow-up assessment involved a more detailed assessment of attitudes to the TH intervention. This indicated that those with diabetes and who held more negative beliefs about acceptability of the TH service were more inclined to withdraw from TH. Conversely, those with positive beliefs around TH experienced increased accessibility to healthcare services, were more satisfied and held more positive beliefs about privacy and comfort of TH were less likely to withdraw. These more detailed findings suggest that not only is complexity and a change in procedure that leads to withdrawal from TH but that there needs to be a sense of gain in the healthcare service and no intrusion and reduction of privacy for TH to be retained.

In considering the introduction of TH into healthcare, these findings taken together emphasise the need to address patient concerns regarding complexity and changes in routine, those expressing dissatisfaction by withdrawing, as well as perceptions of the potential benefits of TH. The issue of withdrawal is not insubstantial and withdrawal once TH is installed is costly and in turn will reduce the likelihood of TH being found to be cost effective.

### **Implications**

The current study addresses a novel and often neglected area of research that has important implications for patient care and policy implications for mainstreaming TH as a service. Despite the widely held assumption that all those eligible for TH would accept and use the service, there are a proportion of patients who refuse to participate in trials evaluating TH and a further group of participants identified in the current study, who agree to having TH installed in their home and then reject the service and ask for the equipment to be removed. These findings are particularly important in light of attempts to mainstream TH. These findings suggest that there may be sub-groups of participants who would not benefit from the provision of TH alone and would need additional support that focused on addressing the factors identified in this paper.

### **Limitations**

This study was a sub-study in a larger trial and so was not specifically designed to examine factors associated with patients' refusal to manage their health using TH technologies. In this context, rejection of TH outside of trial conditions may differ to the results reported here. There is also a risk that not all relevant factors were included in the study, and that some of the variables were not identified as significant because of insufficient power due to the small sample size, this was especially the case with the short-term follow up.

Moreover, reasons for withdrawing from a trial are sometimes multi-faceted and not easily categorised into one reason. However, despite this limitation, the strength of recruitment from different WSD sites allowed a good case mix of deprivation, health status, rural and urban living. This meant that not only was there variability in these factors to test their relative importance in predicting TH rejection, but also that the results have good external validity and so the findings should translate to other GP practices and individuals. Identifying factors that predict refusal of TH, over and above socio-demographic differences using valid and reliable measures, has wide ranging implications for the success of mainstreaming these devices throughout the healthcare service.

### **Conclusions**

There are populations who will withdraw from a TH intervention even after having TH installed in their home and gaining some experience from the TH service. Actively rejecting TH is a neglected issue in research and service provision. We found that not only was this the most common reason for withdrawing from a trial of TH, but there were individual differences, particularly participants beliefs about TH were the most important predictors of TH rejection. These findings have implications for mainstreaming and suggest that encouraging realistic and helpful beliefs about TH will minimise refusal and wasted resources.

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## Ethical approval

The study was approved by Liverpool Research Ethics Committee (Ref: 08/H1005/4).

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