Challenges in evaluating telehealth through RCT-the problem of randomization

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Abstract. Telehealth is heralded as a panacea to control burgeoning demand on healthcare resources and lack of streamlining in care delivery. However, evaluating the effectiveness of telehealth on health and care delivery outcomes through randomized controlled trials (RCTs) has been an issue of contention. This research investigates the issues that affect telehealth evaluation.

The strategy adopted in this research involved conducting a qualitative longitudinal case study, in the UK. Data was collected through focus group discussions and interviews; and analyzed thematically.

The results of this research indicate that there are both practical and methodological issues that affect evaluation of telehealth through RCT in healthcare. Addressing these issues is vital in order to understand how an evaluation strategy should be deployed, and whether it is suited to the healthcare context.

Keywords. Telehealth, Randomized Controlled Trail, Technology evaluation, Longitudinal case study.

Introduction

Telehealth accomplishes delivery of care virtually by means of telecommunication technology [1-5]. Potential advantages of telehealth include improved clinical outcomes, reduced number of unplanned hospital and A&E admissions, allowing clinicians to monitor patients' health and deal with case load more efficiently; and enable patients to be more independent and self-manage their conditions [6,7].

To evaluate benefits of telehealth, approaches such as randomized controlled trial (RCT) are often employed. The strength of a RCT is random allocation of participants and being blind or double blinded, thus, reducing the chances of bias and eliminating potential impact of factors other than the intervention [8-11].

However, RCT's inherent design requirement of careful selection meeting strict eligibility criteria and randomization of participants often causes delays, impacts the sample size and genrelasibility of the findings [12-21]. These problems often cause many trials to terminate prematurely. In addition, lack of assessment of the impact of contextual issues on intervention renders it a less desirable strategy to evaluate technological intervention in healthcare [12-16].

Recognizing the issues surrounding RCT and acknowledging that RCT in healthcare is recognized as a 'gold' standard among the various evaluation strategies available, and widely used in pharmaceutical industry, it is of interest to understand

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why applicability and appropriateness of RCT as an evaluative tool is questioned when applied to evaluate healthcare technological intervention. This research explores this question by asking clinical front line staff involved in deploying telehealth and evaluating it through RCT about their views on integrating evaluation methodologies such as RCT into mainstream services.

The case study in this research focuses on initiative taken by a Primary Care Trust (PCT) in England, U.K., to evaluate the effectiveness of telehealth service implemented alongside case management for patients with Chronic Obstructive Pulmonary Disease (COPD) through RCT. The RCT aimed at answering whether patient's clinical health outcome improved through the use of telehealth significantly, and whether reduced healthcare utilization was achieved. The design of RCT involved recruiting 500 patients and comprised of two arms. The trial was terminated after 12 months due to lack of patient recruitment and staff buy-in.

1. Methods

Longitudinal data was collected by conducting focus group discussions (FGDs) and interviews, in which a purposive sample of staff participating in this project were recruited. This approach allowed staff to elicit their initial views and apprehensions over RCT deployment; and later, reflect on the outcome of the project and how the processes of care delivery changed over time. The staff involved included Community Matrons (CM), Congestive Heart Failure (CHF) nurses, Chronic Obstructive Pulmonary Disease (COPD) nurses, and Community Support Workers (CSWs).

Three FGDs were held at the beginning of the project in July 2009. The FGDs were held at PCT, and a total of 16 staff took part. Each discussion lasted 50-70 minutes in duration. In June 2010, eight in-depth semi structured interviews were carried out. Interviews were held at the participants' work place to minimize disruption to their daily work. Each interview lasted between 30-50 minutes. All focus group discussions and interviews were audio recorded and transcribed. They were analyzed using thematic analysis approach [22].

2. Results

The emergent issues were categorized into two main themes: practical issues and methodological issues.

2.1. Practical issues

Staff commented that the deployment of the RCT should have been timed appropriately:

"*it (RCT) maybe should have been a little bit before they actually gave us the boxes(telehealth equipment) in the first place ...but it (RCT) came in, right in the middle of saying, right, here's the boxes; you can give them to patients that you clinically feel require it, so we were doing that……and then all of a sudden they're like no, you can't do that now because they're part of this trial*" CHF nurse (Interview8 2010).

Staff argued that their expertise was challenged when expected simultaneously to familiarize not only with evaluation of telehealth with RCT but also installation and other telehealth service procedures:

"*it would have been better if telehealth had been embedded in more and more units out there, to then have introduced the RCT as an additional evaluation tool on an established process and protocol.*" Telecare lead (Interview4, 2010).

The RCT was argued to decrease healthcare professionals' efficiency due to added workload of patient assessment and recruitment and lack of appropriate support and training:

"*....we do have patients who will need help filling in the questionnaires (for assessment, recruitment and consenting to take part in the trial)..so there is going to be workload implications*"CM2 (FGD3 2009).

Nurses argued that RCT consenting and going through the initial assessment was required to fit in with the clinical encounter, and such issues were argued to have hindered the recruitment of patients by healthcare professionals as at times talking to patient about RCT did not seem appropriate, for instance:

"*…the police were there and it was all chaotic- antisocial behavior, it was not appropriate on that day so I have it (get consent and complete questionnaires) to do in my next visit*" COPD nurse (FGD3 2009).

The RCT had implications on distribution of patients in nurses' caseload and this caused concern:

"*Obviously because the patient have been picked up randomly so one matron might have ten patients in the caseload who have been chosen in the trial and then there is another matron who might have two.*" CHF nurse (FGD1 2009).

2.2. Methodological issues

Staff argued that RCT lead to inequitable access to healthcare resources as people from ethnic minorities were not able to take part in the trial due to the selection criteria, despite the fact that large part of population is comprised of people from ethnic minorities and have a high prevalence of the disease:

"X (area name) *got a big Asian population as well ....Chinese and all sorts*" CHF nurse (FGD2 2009)

Staff further argued that gaining consent from all the patients for RCT recruitment would be unfavorable towards patient's emotional and mental wellbeing:

"*I don't understand why everybody has been consented. Because I feel there is a psychological element there…..I think that does affect them.*" CM (FGD1 2009).

Some nurses expressed concern regarding telehealth service being withdrawn from the patients once the trial was over as patient might start to rely and depend on it.

Staff argued that the effectiveness of telehealth should be evaluated by using alternative methods other than RCT, and which aim to seek user opinion prior to launch of an intervention:

"*Building evaluation, not maybe an RCT, but have some really robust local evaluation that you can use…to know that it's working and need to know that it's beneficial*" Telehealth Project Manager (Interview3 2010)

3. Discussion

This study highlights that while healthcare staff perceive the value of research to assess the effectiveness of interventions such as telehealth, they argue that where technology evaluation is involved, different methods should be applied [13,20].

Practical issues for RCTs relate to effective planning of the trial to take in to account the staffs' existing work load, the complexity of care delivery and ensuring the telehealth intervention has been implemented and resourced effectively including staff engagement with the RCT concept to ensure they are comfortable with the nature of the trial.

Whilst these practical issues deal with design and operationalization of the RCT protocol they are crucial to both the success of the trial (recruitment of patients and continuing engagement of staff) and to the ability to interpret meaningful results from trial outcomes (knowledge that the telehealth intervention was provided appropriate is important for drawing meaningful conclusions about the effectiveness of the intervention). In this instance the failure to manage these components effectively led to the premature termination of the trial.

Importantly, staff identified methodological concerns linking to the value of the findings when a large proportion of the potential treatment population were excluded from the RCT. These concerns demonstrated an insight by staff as to how the results from the RCT could be generalized and used to influence continued provision of the telehealth service, despite a lack of knowledge of its effectiveness in a significant proportion of the treatment population who are likely to have different health and communication needs.

Hence, this study highlights that it is important to debate which evaluation methods should be adopted especially when evaluating technological interventions in a complex healthcare environment. This debate is particularly timely given the current economic climate and the need to invest in evaluation methods that are likely to produce findings of greatest value.

Whilst RCTs remain the gold standard of evaluation it is essential that resource invested in such trials is used well, with consideration given to what steps can be taken to better educate and prepare clinical staff in evaluation methodologies, and that staff are involved in the design of the RCT to ensure it is effectively resourced and managed and can integrate with existing workloads.

Given the complexity, large samples sizes and practical and methodological limitations of conducting RCTs it is important for the funders of research to consider whether this is the appropriate methodology to adopt. There are alternative procedures and strategies to assess the effectiveness of technological interventions such as employing different qualitative evaluation methods to assess the impact of intervention, methods that recognize evaluation strategy as social-practice, and methods that enable consideration of contextual issues [12,13,16,18-21] which may offer greater value findings to those responsible for commissioning and delivering care.

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