Telehealth for chronic disease management: Do we need to RE-AIM?

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Abstract. An increasing number of individuals are living with long term health conditions which they manage most of the time by themselves. This paper evaluates the use of information and communications technology platforms to provide evidence-based programs to help people with chronic disease to self-management these. It describes two different self-management strategies for chronic conditions, and the evaluation of their implementation in clinical trials, specifically in terms of reach, implementation fidelity, adoption and user perceptions. It also discusses the challenges in replicating trial findings in the real world, using the RE-AIM framework.

Keywords. Telehealth, chronic disease, self-management, implementation

Introduction

One of the major epidemiologic trends of the current century is the rise of chronic diseases in Australia and world-wide. Increasing prevalence of conditions such as cardiovascular disease (CVD) and type 2 diabetes mellitus (T2DM) is placing enormous financial and societal burden on many countries. To address the spiraling demand on health service resources, there is an urgent need for alternative, affordable strategies to support the management of these diseases effectively in the community. National and international attention is increasingly being focused on utilizing the advances in information and communication technologies (ICT), to design and develop new platforms for chronic disease management. The explosive growths of the Internet, personal computers and other digital devices, mobile phones and associated software applications continues unabated and have resulted in the emergence of technologies that could be used outside the clinical setting to monitor health status, improve clinical outcomes and augment home-care and self-management.

Many innovative health strategies and interventions which exploit the current advances in ICT have been developed and tested, with varying success. In general

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however, evidence suggests that ICT supported health interventions can increase efficiency of chronic health provision without compromising the quality of care delivered [1, 2].

Many researchers who develop disease management interventions intend to promote evidence-based interventions to the broader population from which the study sample was drawn or the public health or clinical practice settings in which the intervention was originally tested. The assumption has often been that tools and interventions deemed efficacious within clinical or community-based trials would be readily transmitted to the field. There is, however, a lack of "fit" between an intervention/ research design on the one hand and the realities inherent to the ultimate target practice setting and the information needed by policymakers on the other hand. This often leads to low adoption and implementation in the real world [3]. Even when interventions have been tested within the scope of clinical trials, the development of knowledge to support their broader effective implementation in the real-world often remain unaddressed [4]. This disconnect in what is supposed to be a linear transition between efficacy and effectiveness studies has also been pointed out by Glasgow and colleagues [5].

There are many interacting reasons for the general failure of health interventions to translate into practice, including economic and social policy, as well as scientific factors [6]. The aim of this paper is to present the evaluation of two different strategies for supporting self-management of chronic conditions; these include a platform utilizing mobile phones and the internet to deliver cardiac rehabilitation (CR) at home, and an automated telephone linked care system for supporting individuals living with T2DM. We used a 'process evaluation' framework [7] to evaluate specific program components for the two targeted programs, in controlled research settings. Furthermore, we discuss the challenges in replicating trial findings under real world conditions using RE-AIM, a framework for strategizing, operating projects, and making programming decisions to help plan programs and improve their chances of working in real-world settings [8, 9]. According to the RE-AIM framework, to be successfully integrated in health delivery systems, it is important that interventions reach those most in need, are effective, adopted, appropriately implemented and maintained as a complement/alternative to traditional care.

1. Methods

We have investigated two new self-management support strategies utilizing ICT, one for secondary prevention of heart disease and the other for the interrelated condition, T2DM, in terms of efficacy and the feasibility of implementation in the real world:

The Care Assessment Platform (CAP) model was the first to employ new generation smartphones, mobile applications and the Internet to deliver the major components of CR at home. Figure one presents an illustration of the CAP CR program. Patients are provided with a smart phone to enter/monitor their health and exercise at home, using a health diary application. The mobile phone has an integrated accelerometer to measure physical exercise and users are also able to view their progress in graphical form. The patients are additionally delivered with multimedia motivational and educational materials and daily SMS messages through the course of a 6-week CR program. A dedicated Mentor uses an Internet portal to view patients'

progress and monitor their risk factor measurements prior to weekly phone consultations.

Figure 1. An illustration of the CAP CR program. The mobile phone acts as the communication medium through which a mentor provides mentoring and goal setting, daily motivational messages, educational videos and relaxation audio are sent, and self-observations and measurements are entered to a health diary application.

To validate the CAP model for its capacity to improve CR participation rates and demonstrate health benefits similar to that of traditional center-based programs (TCR), the model was tested in a randomized controlled trial (RCT) at Metro North Health and Hospital Services in Brisbane, Australia [10]. The clinical outcomes of the RCT are reported elsewhere [11] and in this paper we present how we used process evaluation methods [7], to explore the potential of implementing CAP CR in clinical practice. We analyzed data from the RCT in terms of the program reach (participation rate), implementation fidelity (usage of the smartphone health applications and measurement devices, and exposure to educational and motivational content), program adoption (participants who adhered to the CR program), and user perspectives. Data were extracted from the CAP server and from evaluation questionnaires administered at the end of the CR program to patients and clinicians.

The Australian Telephone-Linked Care (TLC) Diabetes program is an automated interactive and conversational intervention which uses voice recognition to engage and support individuals living with T2DM to better self-manage their condition. It consists of a computer connected to the phone network, equipped with high quality speech recognition, over 2,000 pre-recorded conversation statements and a database in which each caller's responses are stored to enable tailored feedback and information during a weekly telephone call [12]. Users upload their blood glucose (BG) readings to the TLC server, for use in their pre-scripted conversations with the system, via a Bluetooth device connected to a mobile phone. Figure 2 presents an illustration of the TLC Diabetes program.
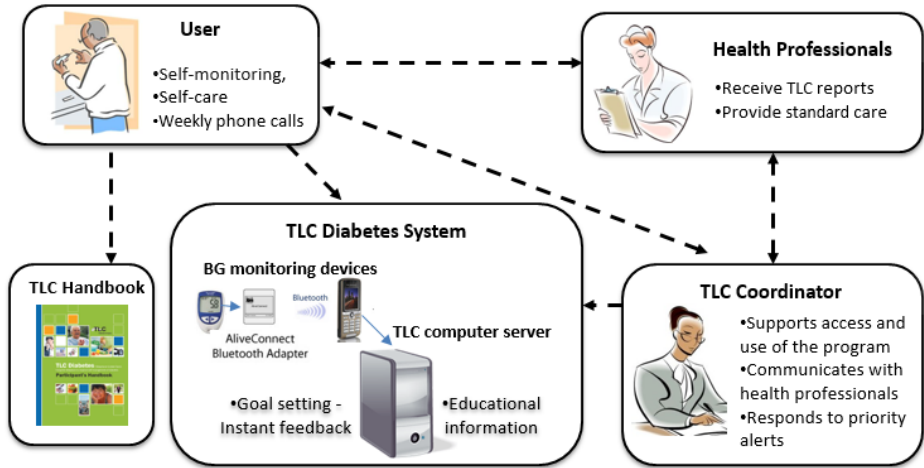
Figure 2. Australian TLC Diabetes program. The program consists of the TLC Diabetes System which includes blood glucose monitoring devices and the TLC server, and support components - the TLC Handbook, TLC Coordinator and Health Professionals

The TLC intervention was also tested through a RCT [13]. The main clinical outcomes are reported elsewhere [14] but we also explored feasibility of implementing such a program in real world conditions through the same process evaluation methods as described for CAP. Usage data were extracted from the TLC server and user perceptions of the TLC Diabetes program were evaluated from responses to a participant evaluation questionnaire administered at the end of the intervention.

2. Results

The results of the CAP RCT demonstrated CAP CR to deliver health outcomes similar to that of traditional center based CR and to significantly improve uptake, adherence and completion rates [11]. Reach, defined as those who enrolled in the trial and by implication intended to participate in CR, was 33% (120/369). The mobile phone and its software applications as well as supplied measuring devices were used daily by >80% of the intervention participants. Motivational and educational text messages were often or always read by 94% of the participants and most participants viewed the multimedia videos in full as required. Adherence to health monitoring and uploading information to the server was exceptionally high (>90%) and showed no decline over the intervention period of six weeks. User perceptions of the mobile phone applications, multimedia videos, relaxation audio and mentoring components of the CAP program were highly positive with all these components rated as easy to use, motivational (especially the inbuilt step counter, the health diary and mentoring), useful, providing a better understanding of their condition and recommendable to other individuals in the same situation. Clinicians perceived the CAP CR program to be a viable alternative to center-based CR programs.

Evaluation of the clinical outcomes of the TLC Diabetes program showed a significant decrease in glycaemic control measured with HbA1c and also a significant improvement in mental health function [14]. Reach in the TLC Diabetes program was high, with a large proportion (70%) of eligible adults with diabetes who registered their interest to hear more about the study, agreeing to take part. Out of the small number who declined to participate, a significant proportion did so for reasons not related to use of the technology system, but rather research-related reasons, i.e. difficulty attending the data collection appointments. TLC system usage was very good with average call duration of 11 minutes and average completion of expected weekly calls at almost 80%. Excellent adoption of the TLC Diabetes program was illustrated by retention of 90% of participants in the program, with only a slight decline in calls made to the TLC system in the second half of a 6-month intervention period. Very high ratings (>80%) of satisfaction, ease of use and perceived advantages offered by the TLC Diabetes program, were achieved.

3. Discussion

Provision of chronic care, particularly for aged populations who often have multiple conditions, requires systems that can directly support people self-manage their long term health conditions. Health services around the world are therefore actively exploring delivery systems which could increase the efficiency of chronic health care provision without compromising the quality of care provided.

This paper uses a process evaluation framework to evaluate two different strategies for supporting self-management of chronic conditions, specifically in terms of reach, implementation fidelity, adoption and user perceptions. The results of the CAP RCT demonstrated CAP CR to deliver health outcomes similar to that of TCR and to significantly improve uptake, adherence and completion rates. Furthermore, using process evaluation methods to explore the potential of implementing CAP CR in clinical practice, results showed that it is an accessible and acceptable option for delivering CR for individuals that are not willing or able to attend TCR. Similarly, the TLC Diabetes program demonstrated efficacy in terms of clinical outcomes, very high reach with individuals at risk of diabetes complications and good level of implementation fidelity and adoption. The results demonstrate the potential for this type of program's scalability, and present a promising approach to delivering self-management support to the growing number of individuals living with T2DM.

The investigation of programs such as the CAP CR and TLC Diabetes programs is the first step in the important process of building the evidence base that could eventually lead to their integration into existing health care systems. Nonetheless, the two mentioned interventions are two amongst a multitude of other ICT- supported health programs available today, but the need to establish criteria for translation and dissemination into the real-world of clinical care is not answered in many cases. Often such programs are supported by time-limited external resources, and even if proven effective, are shelved when the projects are completed because they cannot easily be integrated and supported by ongoing care services [2].

Evaluation is needed to explore how to establish and maintain interventions in community and healthcare settings, with the required systematic consideration of the individuals who might use it, the specific behaviours that are targeted for change, the type of technologies that will be used, the time frame of the program, the costs, and the

strategies to integrate the programs into a broader program of comprehensive care. Additional factors to be considered are security, governance and confidentially of data, which are more difficult to apply outside the controlled environment of clinical trials.

Goode and Eakin offer recommendations on what is optimally involved on the part of the researchers to facilitate successful dissemination efforts [15]. Using the RE-AIM model [16], they emphasize the importance of substantial initial and ongoing research provision around program uptake, delivery, and evaluation. RE-AIM is an evolving framework which has been extensively used in the literature for guiding evaluations and to inform program implementation decision-making. According to the RE-AIM framework, to be successfully integrated in health delivery systems, it is important that interventions reach those most in need, are effective, adopted, appropriately implemented and maintained as a complement/ alternative to traditional care. The RE-AIM framework would therefore be valuable to facilitate and evaluate future real world implementation of the two interventions included in this paper, in terms of:

Reach

In terms of CAP CR and the TLC Diabetes program, barriers and enhancers need to be investigated especially in health regions with limited access to health services. The ability to deliver both these interventions without ongoing face to face contact, not only provides an opportunity to reach large numbers of people, but may be particularly useful in recruiting people who do not have health care services available due to remoteness.

Effectiveness

Effectiveness under real-world conditions needs to be evaluated in terms of relevant outcomes when compared to the original more controlled evidence-based trial outcomes. Replication studies would establish whether the effect sizes observed in the current studies can be repeated.

Adoption

The proportion and representativeness of settings or program providers (e.g. health organizations, health departments, general practitioners etc.) that take up (adopt) these programs for delivery need to be determined. Care systems have been relatively slow to adopt self-management programs and to integrate them into more comprehensive care for patients with chronic disease. An important issue to consider in future development of programs such as CAP CR and TLC Diabetes is that technological interventions could be perceived as undermining important aspects of care, with implications for caring roles [17]. This highlights the importance of carers' perspectives when designing, implementing and evaluating such interventions, and the need for programs to also meet carers' requirements.

Implementation

In future studies, it needs to be verified whether implementation of the interventions is feasible in various contexts and groups, including remote areas and minority groups.

Technologies such as those utilised in CAP CR and TLC Diabetes allow program components to be delivered automatically, providing a specified dose, depending upon participant actions. Tailored variables can be measured and used to assign an optimum dosage of program components (albeit for CVD or T2DM management) to participants in real or near-time.

Maintenance

Further studies are needed with longer follow up periods to establish whether the individual behavioural changes seen in the current research are maintained in the long term. On organizational level it would be necessary to track the extent to which these programs become a routine part of existing delivery services. No amount of excellent intervention research will contribute to improved health outcomes without effective and sustainable translation into policy and action. At the Australian state and federal level, policymakers are cutting budgets and may be reluctant to shift even modest resources from the core activities. To move forward, the necessary funding will have to be obtained from government and private agencies.

4. Conclusion

As the prevalence of chronic diseases continues to grow, with corresponding increase in human and societal costs, there is an urgent need for effective, convenient, easily accessible, and scalable approaches for improving self-management of these diseases.

Despite differences between different chronic conditions, the expectations on the people living with these diseases are similar: to make day-to-day decisions in response to changes in disease condition, to alter behaviour, and to deal with social and psychological impacts of living with the conditions. The CAP CR and TLC Diabetes programs, even though using a variety of different technologies, have shown potential for expanding care from traditionally delivered face to face encounters to care that reaches into the patient's home and community. However, challenges exist in replicating trial findings in the real world. If properly developed, implemented and evaluated, according to a strategic tool such as the RE-AIM framework, ICT platforms such as these have excellent potential to support and improve the self-management of chronic disease.

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