

MedFit: A formative research process to develop a mobile-application based intervention for Cardiovascular Disease

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Abstract:

Cardiovascular disease (CVD) is the most common cause of mortality in Ireland, accounting for one third of all deaths and one in five premature deaths [1]. With the prevalence of CVD so high, not only in Ireland but across the world, cardiac rehabilitation has never been so important as a continuous process of care. The main purpose of cardiac rehabilitation is to prevent a further cardiac event and improve the person's quality of life. However, uptake of such programmes remains low. mHealth technologies may tackle some of the issues relating to poor uptake and low adherence, such as accessibility and affordability. This paper outlines the formative research process to develop a mobile-application for cardiovascular rehabilitation.

Introduction:

Cardiovascular disease is the leading cause of premature death and disability in Europe, accounting for four million deaths per year and costing the EU economy almost €196 billion annually [2]. Exercise-based Cardiac Rehabilitation (CR) is used to reduce the impact of CVD and to promote healthy behaviours and active lifestyles for those with CVD [3]. Whereas, CR improves mortality and morbidity rates, adherence within these programmes is generally low [4]. Some of the more common issues identified with adherence to CR programmes relate to accessibility and parking at local hospitals, a dislike of group environments and work or domestic commitments [4].

Mobile health (mHealth) is an emerging area of healthcare and is defined as "*medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants and other wireless devices*" [5]. mHealth technologies have the ability to make healthcare more accessible, affordable and available to the public [6]. Although this is still a developing area of research, literature in the area of internet and mobile-based health interventions has found that such tools can be useful in supporting the self-management of chronic disease [7][8].

Within this paper we outline the development work within the MedFit project. MedFit is designed to utilize the expertise in a community-based medical exercise programme, called MedEx, and the Insight Centre for Data Analytics, to allow people with CVD to participate in an exercise-based rehabilitation programme remotely, through a specially designed Android App called MedFit. The MedFit App offers the potential to make exercise-based rehabilitation programmes more effective by making them more accessible, more personalised and more interactive, by providing real-time support and feedback for participants.

In order to develop an evidence-based effective mobile App for CVD embedded within health behaviour change theory, it is important to engage in a formative research process. Formative research involves key research activities including, a systematic review of current literature, usability testing, feasibility studies as well as extensive piloting and user validation. The key stages are outlined below and provide a best practice framework for App development within a health behaviour change and public health setting.

Formative Research Process:

The formative research process is a critical step in the development of health behaviour change interventions and consists of 4 key stages; development, feasibility/piloting, evaluation and implementation [9].

The first stage of the research involves conducting a systematic review in order to identify the relevant, existing evidence base, as well as potential gaps in the literature [9] (see Figure 1.). Within MedFit a crucial step of the development was to systematically examine previous research to assess mHealth and eHealth (electronic health) interventions to identify what behaviour change techniques are applied and to identify how effective they are in delivering meaningful long term behavioral change. The review entitled a 'Systematic review of the use of Behaviour Change Techniques (BCT's) in physical activity eHealth interventions for adults with cardiovascular disease' was thus registered in an online systematic review protocol database 'Prospero' as per best practice guidelines to aid transparency within the development process. This research will identify the most effective BCT's in eHealth interventions for CVD patients. Subsequently the results of this study will then be translated into technical requirements to inform the development and functionality of the application 'MedFit'. This means that both the technical aspects of the application (i.e., push notifications and the user interface) as well as the tailored interactive content are all based within an evidence and theory-based framework of health-behaviour change. To date, preliminary searches have been carried out, piloting of the study selection process, as well as formal screening of the title and abstract of search results against the eligibility criteria.

In the next stage of the development process, the feasibility and acceptability of the prototype application will be tested in focus groups and subsequently in feasibility and pilot trials prior to the full scale trial. The focus group content will be developed and informed using models of technology acceptance. This stage of user validation through the focus groups is a crucial part of the user-led formative research and design process, with the purpose being to gain feedback on the first prototype of the mobile App. This feedback will be translated into feasible technical improvements through close collaboration with the technical design team, who will adapt and make modifications and upgrades to the app based on the patient feedback and comments from the focus group. This user validation will be an iterative process with subsequent rounds of focus groups, where the initial group are brought back to view the changes and additional features added to the App and provide additional feedback on these. This iterative design process with the end-user allows for the custom design and creation of a truly patient-centric home-based exercise-rehabilitation CVD platform.

Following this, the updated version of MedFit App will be evaluated through small-scale feasibility trial and pilot trials as per the Medical Research Council Guidance for the development and evaluation of complex behavioural change interventions [9]. A feasibility trial will be conducted in order to assess the intervention components and to assess acceptability, likely rates of recruitment, retention of participants and to calculate appropriate sample sizes [9]. The feasibility trial will be conducted with collaborator hospital partners in the Dublin Region, with approximately 40 participants (intervention N=20, Control N=20) for a period of a minimum of 4 weeks to trial user engagement and adherence to using the app. Such research may identify any methods or protocols which need modification and also how changes might occur [10]. Following the feasibility trial medical practitioners will be approached for feedback in terms of likely rates of recruitment, retention of participants and any informal feedback they may have received from patients regarding MedFit. This will then inform the development of the pilot MedFit intervention, before a final full scale intervention can be carried out to evaluate the mobile application's effectiveness.

Conclusion:

As MedFit is currently an on-going and active research project, this research will focus on the phases of development and evaluation of a complex mHealth intervention. This entails the design process, first alpha-version of the App, focus group feedback, as well as a framework for early stage usability testing.

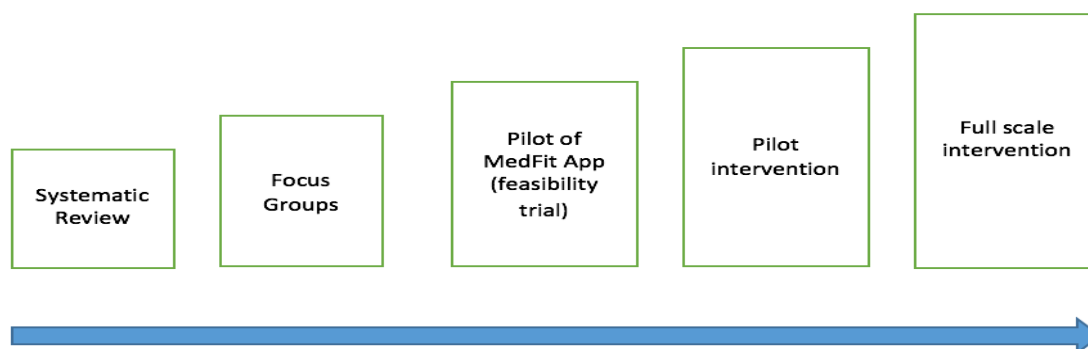


Figure 1. Stages of the formative research process

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References:

1. Department of Health and Children. (2010). *Changing Cardiovascular Health. National Cardiovascular Health Policy 2010-2019*. Dublin: Government Publications.
2. Nichols M, Townsend N, Luengo-Fernandez R, Leal J, Gray A, Scarborough P, Rayner M (2012). *European Cardiovascular Disease Statistics 2012*. European Heart Network, Brussels, European Society of Cardiology, Sophia Antipolis
3. Balady, G., Ades, P., Comoss, P., Limacher, M., Pina, I., Southard, D., et al. 2000. Core components of cardiac rehabilitation/ secondary prevention programs: a statement for healthcare professionals from the American Heart Association and the American Association of Cardiovascular and Pulmonary Rehabilitation Writing Group. *Circulation*, 102: pp.1069-1073.
4. Dalal, H., Zawada, A., Jolly, K., Moxham, T., & Taylor, R. 2010. Home based versus centre based cardiac rehabilitation: Cochrane systematic review and meta-analysis. *British Medical Journal*, pp.1-15.
5. World Health Organisation. 2011. mHealth: New horizons for health through mobile technologies. *Global Observatory for eHealth Series (Vol.3)*. Geneva: WHO.
6. Akter, S., D'Ambra, J., & Ray, P. (2010). User perceived services quality of mHealth services in developing countries. *Proceedings of the Eighteen European Conference on conference on Information System*. Pretoria, South Africa: University of Pretoria.
7. Fanning, J., Mullen, S.P. and McAuley, E. 2012. Increasing physical activity with mobile devices: A meta-analysis. *Journal of Medical Internet Research*, 14(6), pp.61-71.
8. Omboni S, Gazzola T, Carabelli G, Parati G. Clinical usefulness and cost effectiveness of home blood pressure telemonitoring: meta-analysis of randomised controlled studies. *Journal of Hypertension*, 31(3), pp. 455-467.

9. Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ: British Medical Journal*, 337, a1655. <http://doi.org/10.1136/bmj.a1655>

10. Bowen, D. J., Kreuter, M., Spring, B., Cofta-Woerpel, L., Linnan, L., Weiner, D., Bakken S., Kaplan C., Squiers L., Fabrizio C., and Fernandez, M. (2009). How We Design Feasibility Studies. *American Journal of Preventive Medicine*, 36(5), 452–457. <http://doi.org/10.1016/j.amepre.2009.02.002>