Telehealth for patients at high risk of cardiovascular disease: pragmatic randomised controlled trial

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Abstract

Objective To assess whether non-clinical staff can effectively manage people at high risk of cardiovascular disease using digital health technologies.

Design Pragmatic, multicentre, randomised controlled trial.

Setting 42 general practices in three areas of England.

Participants Between 3 December 2012 and 23 July 2013 we recruited 641 adults aged 40 to 74 years with a 10 year cardiovascular disease risk of 20% or more, no previous cardiovascular event, at least one modifiable risk factor (systolic blood pressure ≥140 mm Hg, body mass index ≥30, current smoker), and access to a telephone, the internet, and email. Participants were individually allocated to intervention (n=325) or control (n=316) groups using automated randomisation stratified by site, minimised by practice and baseline risk score.

Interventions Intervention was the Healthlines service (alongside usual care), comprising regular telephone calls from trained lay health advisors following scripts generated by interactive software. Advisors facilitated self management by supporting participants to use online resources to reduce risk factors, and sought to optimise drug use, improve treatment adherence, and encourage healthier lifestyles. The control group comprised usual care alone.

Main outcome measures The primary outcome was the proportion of participants responding to treatment, defined as maintaining or reducing their cardiovascular risk after 12 months. Outcomes were collected six and 12 months after randomisation and analysed masked. Participants were not masked.

Results 50% (148/295) of participants in the intervention group responded to treatment compared with 43% (124/291) in the control group (adjusted odds ratio 1.3, 95% confidence interval 1.0 to 1.9; number needed to treat=13); a difference possibly due to chance (P=0.08). The intervention was associated with reductions in blood pressure (difference in mean systolic −2.7 mm Hg (95% confidence interval −4.7 to −0.6 mm Hg), mean diastolic −2.8 (−4.0 to −1.6 mm Hg); weight −1.0 kg (−1.8 to −0.3 kg), and body mass index −0.4 (−0.6 to −0.1) but not cholesterol −0.1 (−0.2 to 0.0), smoking status (adjusted odds ratio 0.4, 0.2 to 1.0), or overall cardiovascular risk as a continuous measure (−0.4, −1.2 to 0.3)). The intervention was associated with improvements in diet, physical activity, drug adherence, and satisfaction with access to care, treatment received, and care coordination. One serious related adverse event occurred, when a participant was admitted to hospital with low blood pressure.

Conclusions This evidence based telehealth approach was associated with small clinical benefits for a minority of people with high cardiovascular risk, and there was no overall

improvement in average risk. The Healthlines service was, however, associated with improvements in some risk behaviours, and in perceptions of support and access to care.

Trial registration Current Controlled Trials ISRCTN 27508731.

Reviewer: 1 - Patient and Public Reviewer

Recommendation: Comments:
Dear author(s), Thank you for sending in the manuscript. I am reviewing the manuscript based on my own patient experiences and application of "general" patient experiences in healthcare practice and policy. Below are my comments:

Relevance: It is relevant for patients with cardiovascular risk or depression to get support regarding lifestyle management and selfmanagement. Moreover, I think it is essential to determine if technological interventions would be suitable to help patients in terms of effectiveness. The study is definitely relevant for carers and the health system to determine effects of eHealth interventions on costs and efficacy of care.

Missing areas: Compliments on the extensive research approach of the study. All factors which are involved in cardiovascular risk are measured. For me one of the missing areas in the research design is giving attention to and questioning the reasons for patients to participate (e.g. their motivation). Moreover, I think it would be beneficial to also know why a patient does not want to participate in the study, how the participating patients experienced the intervention (in terms of experiences, not just satisfaction) and/or why patients stopped participating in the study.

Feasibility of the intervention: The intervention is quiet low-profile for influencing such a large amount of lifestyle factors: diet, exercise, smoking etc. (e.g. in terms of frequency and quality). Based on my experiences, I think that patients will not be motivated enough with this intervention to change such stubborn lifestyle behavior. I think it would be good to also include physical consultations or fine-tune the Healthlines programme with regular care to enable patients to really feel and experience the support in real-life and also have a more efficient/effective interaction with regards to psychosocial factors, which greatly influence lifestyle behavior.

I could not read in the manuscript how tailor-made the advises of the Healthlines health advisors were. I read it as if the participants goals and advises were based on their biomedical status and the algorithm. In that case, I would advise to also include their personal goals in life in determining the advises, because that is what drives people to change (according to my opinion). For influencing behavior, it is really necessary to give tailor-made advises and connect the advises to the personal goals of the patients.

Outcomes: I would have also liked to see what motivation the participants had regarding their disease, prior to the intervention and afterwards, because I think this determines how well you perform in care processes/ patient education, and the motivation can also be influenced by the intervention and thus measured afterwards. One could use the PAM-13 to measure this.

Suggestions: I would show more details on how tailor-made the intervention was for the participants. If possible, I would show more information about how the patients experienced the intervention (in terms of process/experiences). Describe more what physical consultations and other forms of care were given next to the intervention. If applicable, describe more to what extend patients were involved in designing the intervention.

To conclude, I really think it is good to see prove that this intervention had a minor effect on the participants, because it shows that eHealth is hard to implement and that involvement of the patients' perspective is really necessary for designing a technological intervention and fitting it to patients' needs.

Yours sincerely, Thomas Vijn
Patient Reviewer
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