Is Home Telemonitoring Feasible in the Care of Chronic Diseases - Insights into Adherence to a Self-management Intervention in Renewing Health Finland Trial

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Abstract. eHealth studies typically suffer from high attrition rates. **Objective** To investigate type 2 diabetes and heart disease patients' adherence to a self-management intervention that combined health coaching and telemonitoring. **Methods** Renewing Health Finland was a 12-month randomized controlled trial to improve quality of life (QoL) and/or HbA1c of 595 patients with chronic conditions. The intervention consisted of (1) weekly measurement of health parameters (2) health coaching every 4–6 weeks. Adherence to telemonitoring was defined as the percentage of weeks with at least one reported health measurement. Adherence to coaching was defined as the number of received calls. **Results** The median percentage of monitored weeks was 65 % without time-dependent attrition. 66 % of participants received 7–11 calls that corresponds to the predefined coaching schedule. Adherence did not correlate with QoL or HbA1c. **Discussion** Our results indicate that the intervention in the Renewing Health Finland trial was delivered almost with planned intensity.

Keywords: Adherence · Telemonitoring · Health coaching · QoL · HbA1c · Type 2 diabetes · Heart disease

1 Introduction

Increasing burden of chronic diseases combined with aging population and reductions in health care resources create a need to identify care models that respond to the growing demand while maintaining and/or improving the quality of the care.

Chronic care models that incorporate remote patient monitoring have shown promise in the past decades. Specifically telemonitoring interventions that involve measuring and reporting disease-specific information remotely and transferring the data to health care providers have been widely studied with positive outcomes among a variety of chronic conditions including diabetes, hypertension, chronic obstructive pulmonary disease and heart failure [1, 2]. Such interventions may improve patient's engagement with self-management while sharing the self-monitoring data with health care professionals provides continuous up-to-date information for care professionals to support

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their clinical decision making. However, there is a growing bulk of literature including large-scale rigorous randomized controlled trials that have failed to validate the hypothesized benefits of telemonitoring interventions [3–7].

Attrition is a common feature for eHealth studies; interventions that are not critical but are based on patients' voluntariness and that are easy to discontinue typically suffer from high nonusage rates [8, 9]. While it has been argued that high drop-out rates might be natural feature for eHealth trials, attrition is underreported and poorly understood and might even cause publication bias as it is often associated with failure of the intervention [8]. Study reports show aggregated statistics on usage, however, they often lack longitudinal aspects. Detailed analyses of uptake and possible discontinuation of the intervention are needed and required [10] to understand and further improve the effectiveness of eHealth interventions.

Between 2010–2013, we conducted a randomized controlled trial that assessed the effect of telemonitoring assisted self-management intervention on the quality of life and glycemic control of patients with chronic conditions [11]. Renewing Health Finland was a part of the European research project Renewing Health where nine collaborating countries assessed the effect of telehealth interventions with RCT settings. In conjunction with the majority of the other trials [5], Renewing Health Finland did not find significant effect on primary health outcomes. In this paper we seek to find potential factors that may have contributed to the nonsignificant findings by analysing patients' engagement with the intervention in the Renewing Health Finland trial and investigating the effect of adherence on the health outcomes.

2 Methods

2.1 Renewing Health Finland

Renewing Health Finland (RHF) was a 12-month randomized controlled trial aiming to improve health-related quality of life of type 2 diabetes and heart disease patients and glycemic control of type 2 diabetes patients with an intervention that combined telemonitoring and health coaching. The study population consisted of 308 heart disease patients (ischemic heart disease or heart failure) and 287 type 2 diabetes patients that were recruited from the health care district of South Karelia and further randomized either to the telemonitoring group or to standard care (2:1). Of the 595 participants, 361 (61 %) were men, mean age was 67 ± 9 years and mean BMI was 29.7 ± 5.2 kg/m^2.

The telemonitoring intervention consisted of weekly measurement of weight, blood pressure, blood glucose (for diabetics) and steps (heart disease patients) and reporting the measurements to the back-end systems using a mobile phone. Patients were given a self-monitoring toolbox that consisted of a mobile phone and measurement devices (incl. blood pressure meter, blood glucose meters, scale and a pedometers). In addition, each patient was assigned a personal health coach. During the first study visit the patient and the health coach created a self-management plan that included small achievable health behaviour changes agreed by the patient. The coach called the patients at a 4–6 week interval. During the calls the coach reviewed the goals and provided the patients with information, assistance and support to achieve them. Before

each call, health coaches reviewed patient's self-monitoring data. If the data showed abnormalities, the coach advised patient to contact primary care. If self-measurement data were missing and the patient had received the self-monitoring devices, the coach reminded the patient of the importance of self-monitoring and asked to conduct self-measurements and report them to the system on a regular basis. Detailed description of the intervention and study results is described by Karhula et al. [11]. The telemonitoring system of Renewing Health Finland is depicted in Fig. 1.

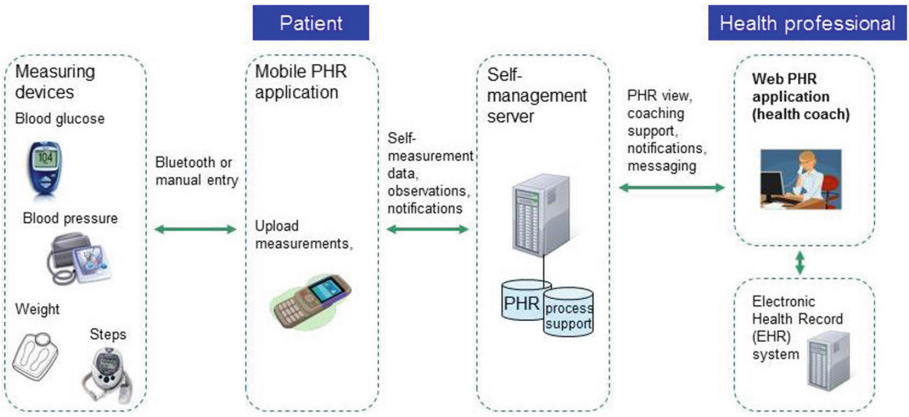

Fig. 1. Technical architecture of telemonitoring system used in Renewing Health Finland

2.2 Measures

The telemonitoring system stored time-stamped self-monitoring data originating from the patients' measurement devices. The log-data from coaching calls included starting time and ending time and status of the call (failed or answered). The logfiles allow detailed analysis of patients' engagement with the telemonitoring intervention in the course of time and the responsiveness to the health coaching.

Adherence. *Adherence to telemonitoring* was defined as the percentage of weeks that included at least one measurement (blood glucose, body weight, blood pressure, steps) reported to the system. Each week was analysed separately and was relative to the individual starting time. In addition, adherence to glucose monitoring was analysed separately as HbA1c was the primary outcome. Adherence to glucose monitoring was similarly defined as the percentage of weeks including at least one glucose measurement.

Adherence to health coaching was defined as the total number of answered health coaching calls and the mean duration of the answered calls. As coaching calls were planned to be done with a 4–6 week interval, each patient was supposed to receive 7–11 calls when the baseline and concluding calls were excluded. The first and last calls were excluded because the control group received the corresponding calls. However, the content of the calls was not similar but control patients received only study-related information.

Quality of Life. The primary outcomes of the Renewing Health Finland trial were the health-related quality of life (QoL) measured using SF-36 and HbA1c. SF-36 was collected at baseline and at the end of the study after 12 months. Physical component score (PCS) and mental component score (MCS) of SF-36 were used in the analyses.

HbA1c. Among type 2 diabetes patients the other primary outcome was HbA1c. Laboratory tests were done at baseline and at the end of the trial.

2.3 Analysis

Firstly, we calculated descriptive statistics for adherence to the overall telemonitoring, glucose telemonitoring and health coaching and illustrated the adherence trajectories over time. Secondly, the association between adherence and following sociodemographic variables were analysed: sex, age, body mass index (BMI), comorbidities, education, familiarity with mobile phone, familiarity with computer, QoL (PCS and MCS) at baseline, and HbA1c at baseline. The analyses were done separately for telemonitoring and health coaching components by employing a t-test and analysis of variance (ANOVA). Thirdly, the correlations between adherence to the intervention and primary outcomes (SF-36 and Hb1Ac) were analysed using ANCOVA which allowed controlling for potential confounders. QoL models were controlled for sex, age, baseline level of QoL and comorbidities. HbA1c models were controlled for sex, age, and baseline level of HbA1c. For HbA1c and glucose monitoring analyses only the type 2 diabetes group was included.

3 Results

3.1 Adherence to Telemonitoring

The majority of participants adhered to weekly telemonitoring (Fig. 2). The median percentage of adherent weeks was 65 %; the 25^{th} and 75^{th} percentiles were 27 % and 85 %, respectively. When only intervention completers were included, the median adherence increased slightly to 67 %. Of the 370 patients, 43 % and 29 % were 70 % and 80 % adherent with weekly telemonitoring. No major attrition was observed in the course of the 12-month follow-up. The retention with telemonitoring was fairly good with the percentage of adherent participants varying from 51 % (week 37) to 68 % (week 6). However, there was a statistically significant linear decrease over time ($\beta = -0.002$ [−0.003to−0.001]). Adherence did not differ between the disease groups and the median number of monitored weeks was 30 in both groups.

Adherence to glucose monitoring among diabetes patients was investigated separately as HbA1c was the second primary outcome for the diabetes group (Fig. 3). Of the 180 diabetes patients, 39 (22 %) did not report any glucose measurements via the mobile application. The median number of glucose monitoring weeks was 17 (33 %). Twenty-six and eighteen percent of the patients were 70 % and 80 % compliant, respectively. Among those who started glucose monitoring, the median number of monitored weeks was 52. Similarly to the overall adherence to telemonitoring,

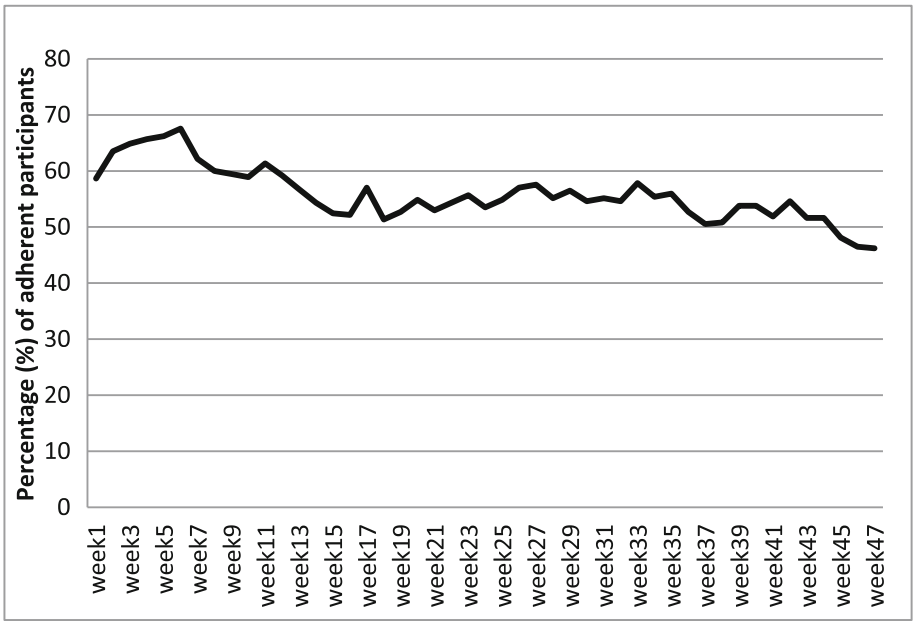

Fig. 2. Adherence to weekly telemonitoring - the percentage of participants who made at least one measurement on a given week (The figure is limited to the week 47 because trial's end-point visits were scheduled to start from week 48)

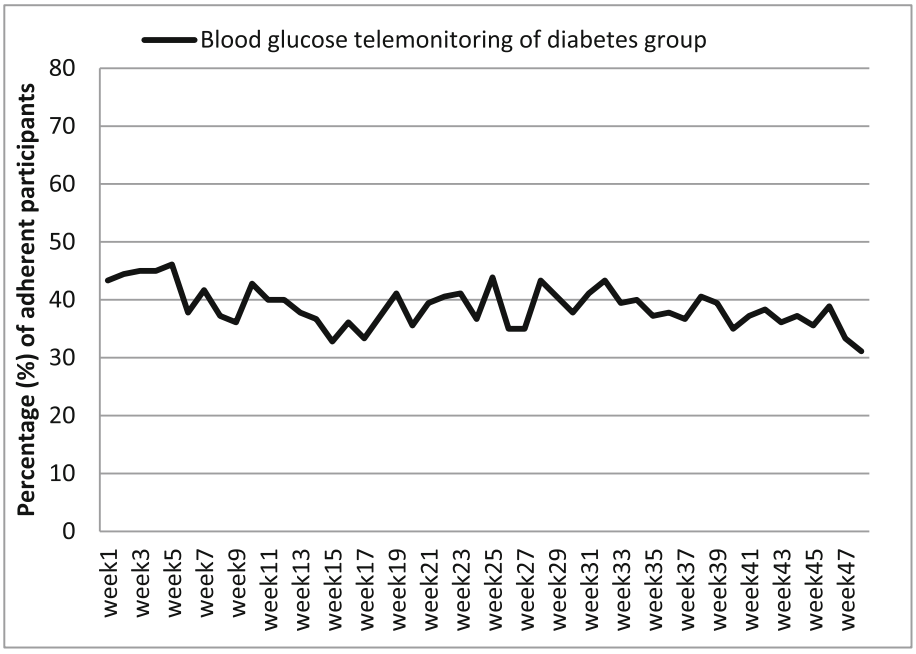

Fig. 3. Adherence to weekly telemonitoring of blood glucose; the percentage of participants who made at least one glucose report on a given week (The figure is limited to the week 47 because trial's end-point visits were scheduled to start from week 48)

adherence to the glucose monitoring remained on a constant level throughout the study; the highest (42 %) and lowest (36 %) adherence rates were observed at weeks 4 and 14, respectively.

3.2 Adherence to the Health Coaching

The mean number of calls was 7.5 when starting and end-point calls were excluded. Sixty-six percent of participants received 7–11 calls which corresponds to the predefined coaching schedule. Eighty-nine percent received at least 6 calls. The mean duration of calls was 26.7 min. There were no differences between the disease groups (md = .19, p = .305 for number of calls and md = .007, p = .993 for the mean duration).

3.3 Predictors of Adherence

Of baseline characteristics, male gender (adherence for males and females: 60 % vs. 50 %, p = .004), younger age (correlation coefficient r = −0.181, p < .001) and familiarity with mobile phones (adherence for familiar and nonfamiliar participants: 58 % vs. 33 %, p = .009) and computers (adherence for familiar and nonfamiliar participants: 63 % vs. 49 %, p<.001) were associated with higher adherence. In total, only 12 patients reported they were not familiar with mobile phones. Education level, BMI, baseline level of QoL and number of comorbidities were not associated with adherence to telemonitoring. Adherence to glucose telemonitoring was associated with age (correlation coefficient r = −0.144, p = .054) and familiarity with computer (adherence for familiar and nonfamiliar participants: 47 % vs. 28 %). There were only 5 diabetes patients who were not familiar with mobile phone; among those the adherence was 7 %. The baseline level of HbA1c did not affect adherence.

Adherence to health coaching was associated with familiarity with computer measured as a higher number (7.8 vs. 7.4, p = .027) and longer duration (27 vs. 26 min, p = .04) of coaching calls.

3.4 The Impact of Adherence and QoL and HbA1c

Figure 4 illustrates the relationship between adherence to telemonitoring and change in quality of life and HbA1c. Adherence to the telemonitoring was not associated with PCS (β = .012, p = .266) or MCS (β = .029, p = .071). When adjusted for baseline characteristics there was a statistically significant positive association between adherence and MCS: $\beta_{adj=.}$.033, p = .042. However, the clinical significance is limited as 10 % unit increase in adherence increases MCS by only 0.3 points. The association with PCS remained nonsignificant β_{adj} = .011, p = .295 after the adjustments. The effects of adherence to glucose telemonitoring or adherence to overall telemonitoring on Hba1c were negative and statistically nonsignificant β = −0.068 (p = .695) and β = −0.0002 (p = .891), respectively.

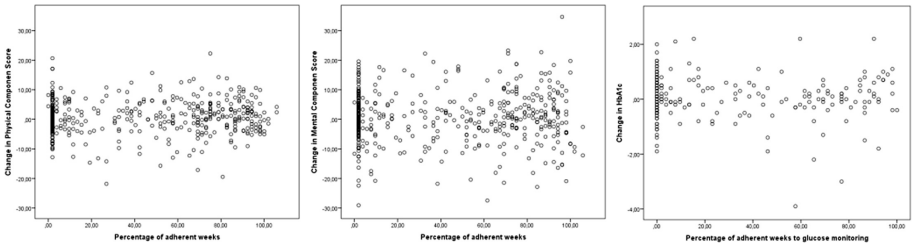

Fig. 4. The relationship between adherence to telemonitoring and change in quality of life

Health coaching measured as the number of answered coaching calls (β = .223, p = .551 for PCS, β = −.132, p = .808 for MCS) and mean duration of calls (β = −.049, p = .368 for PCS and β = .046, p = .557 for MCS) did not correlate with PCS or MCS.

4 Discussion

In this paper we investigated type 2 diabetes and heart disease patients' adherence to a self-management intervention that combined health coaching and telemonitoring, and further assessed the impact of adherence on QoL and Hba1c.

The health coaching component in the Renewing Health Finland (RHF) trial was realized closely as planned. Sixty-six percent (66 %) of patients received 7–11 coaching calls which corresponds to the predetermined 4–6week interval for health coaching, and 89 % of participants received six or more calls indicating the majority of participants missed one call at maximum.

Participants' adherence to the telemonitoring component was moderate: in the course of 12 months the participants conducted telemonitoring on 65 % of the weeks on average. Unlike in many eHealth interventions [8, 12] there was no major attrition towards the end of the trial but the percentage of adherent patients remained 51–68 % over time. In telemonitoring studies adherence rates have been shown to vary from 52 % to 75 % [2, 7, 13, 14]. However, in these studies likewise in a number of other telemonitoring trials, health parameters were monitored on a daily basis that makes the numbers incomparable. Moreover, adherence numbers are typically based on aggregated averages failing to take into account the time effect that was presented in our study.

Glucose telemonitoring was realized with lower adherence rates. Type 2 diabetes patients conducted glucose measurements on 33 % of the weeks on average and only 18 % of the participants were 80 % adherent. The results indicate lower engagement than found in other studies. For example in the DiaTel trial [14], 75 % of non-insulin type 2 diabetes patients engaged in daily glucose monitoring. Low adherence might be related to the unchanged HbA1c levels found in RHF study.

Interestingly, telemonitoring activity did not correlate with QoL or HbA1c but the changes in those health parameters were similar regardless whether a patient was high or low adherent to the telemonitoring component. Our results are contradictory to the

earlier studies showing improved quality of life in telemonitoring trials [1, 15], and improved HbA1c as a result of self-monitoring of blood glucose [16], though the benefits among type 2 diabetics not using insulin are inconclusive [17]. The analysis of predictors of adherence did not shed light on what could explain the lack of this relationship. Participants' baseline BMI and HbA1c levels and QoL were not associated with adherence to telemonitoring. Adherence was neither affected by the number of comorbidities. Of baseline characteristics, sex, age and familiarity with a mobile phone and a computer predicted higher adherence. The results imply that technology-assisted interventions might have potential to appeal younger men who are typically underrepresented and nonadherent to lifestyle interventions. However, the clinical effectiveness of telemonitoring in this context remains questionable.

While self-monitoring is the cornerstone of effective self-management in chronic diseases, it is only as effective as actions taken in response to the measurements [18]. In RHF health coaching was designed to respond to individual needs and empower patients and educate patients for better self-management. Health coaches reviewed patients' self-monitoring data before each call, however, the medication changes that critically affect patient's condition, were not specifically addressed. We do not have data about whether coaching calls resulted in further actions to intensify pharmacological treatment.

5 Conclusions

Our results on adherence indicate that the intervention in Renewing Health Finland was realized with at least moderate intensity. The vast majority of participants received almost a complete health coaching intervention and the adherence to telemonitoring of health parameters was moderate with 34 monitored weeks on average. However, despite their engagement in the intervention, patients did not show improvement in QoL or glycemic control. In fact, the level of adherence to telemonitoring did not correlate with QoL or HbA1c at all. The results suggest that the self-management intervention components (telemonitoring and health coaching) were not effective in improving the quality of life and glycemic control of patients with chronic conditions even when successfully delivered and adhered to. Further research is needed to identify effective approaches to improve the care of chronic conditions.

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