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Design Lessons from an RCT to Test Efficacy of a Hybrid eHealth Solution for Work Site Health[1]

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Abstract

Work site healthy lifestyle interventions hold promise for improving health and employability. As part of a larger employer vitality program and a work site RCT (Randomized Controlled Trial, n=59 intervention arm) to assess cardiac risk impacts, we conducted a design analysis on a hybrid eHealth solution. The control condition was a six weeks waiting list and then start of the hybrid eHealth support (n=57).

Based on preliminary 6 week- and 3 month-results, the hybrid eHealth support generated statistically significant risk factors improvement (like LDL cholesterol). The waiting list condition yielded no significant improvements. The late start after the waiting list did yield significant improvements, but not as large as a direct start. The direct start also appears to yield higher satisfaction and intention to recommend.

1 We are very grateful for the contributions of Kees Schotsman, Niek Stolp, Eelco van Stokkum, Wendy van Leeuwen, Dick Hoeneveld, Lonneke Baas, Bas Gerritsen, Ralph Feenstra, Lotta Breed, Lucas van Vliet and Rudi Westendorp during setup and execution of this study.

Our analysis supports three types of conclusions. First, the hybrid eHealth intervention did significantly improve physical risk factor variables after 6 weeks. Motivation and measurement alone (waiting list) did not. Second, theory on timing of health support for patient appeared generalizable to employees: it did help to offer support at a moment of high motivation, instead of later. Third, a design analysis was conducted regarding service mix efficacy in relation to key requirements for designing ICT-enabled lifestyle interventions. This resulted in several recommendations and improved service adoption.

Keywords: RCT, work site health, service design, multi-channel services, healthy lifestyle intervention

1 Introduction

Cardio-metabolic syndrome hampers the health of almost half of the population by the age of 60. It was estimated that 43% of people >60 years of age have (cardio-)metabolic syndrome (Lakka 2002). This may put them at a 4.26-fold risk of death in an 11 year follow up compared to healthy men, and they are estimated to have a 3.7-fold risk for coronary artery disease and a 24.5-fold risk to develop diabetes-2 (Sattar 2003). The symptoms of metabolic syndrome can become apparent as cardiovascular disease, obesity and/or diabetes type 2.

Metabolic syndrome increases burdens for the individual, as well as burdens on a societal and employer level. It has been estimated that cardiovascular disease leads to 10 additional sick days at work plus 1 month productivity loss while present at work (sickness presenteeism). For diabetes-2 these numbers are: 11 work days and 8 weeks sickness presenteeism (Steenbeek 2010). In general, cardio-metabolic syndrome hampers physical and mental energy, plus employability.

Currently, the majority of the 60+ citizens in the potential work force in the Netherlands are not employed (CBS 2012). This is partly due to health and vitality concerns. For males, the 60-65 age group consumes the largest health care budget, mainly due to cardiovascular disease (Slobbe 2011). Given our aging population and rising health care costs, the need grows for a population which stays healthy and employable longer.

The context of this study is provided by an employee vitality program. Since 2010 the Human Resource (HR) department of Delft University of Technology has piloted an extensive eSupported lifestyle program, which combines coach sessions with electronic dashboarding and self-management. The HR department and company physicians mainly aim at the following part of the employee population: those with increased cardio-metabolic risk (inclusion of >50 participants/year), with increased absenteeism (inclusion of >50 participants/year) plus a minority admission (inclusion of <30 participants/year) with various health issues or interests.

In this HR setting, promising risk factor effects have been measured on a pre-/post-intervention basis (Simons 2013, 2014). Next, an RCT (Randomized Controlled Trial) has been designed, in order to further assess efficacy of the eSupported lifestyle program (Verweij 2011). The primary research question is: are physical risk factors impacted by the intervention? This RCT study design does not aim at the entire

employee population. Rather, it aims at the employee subset which meet the eligibility criteria for cardio-metabolic risk, ability to participate and motivation. The primary study outcomes are total cholesterol and LDL cholesterol, aimed at cardio-metabolic risk.

Besides, there are longer term outcomes. There is an HR interest in exploring impacts on productivity related measures like work engagement (UWES-9, Bakker 2009, Schaufeli 2006) or presenteeism and absenteeism (Iverson 2010). These longer term outcomes are outside the scope of this analysis of preliminary results.

This paper does address another important issue: efficacy of the service mix deployed in the eSupported lifestyle intervention. We combine preliminary, short term results from the RCT measurements with a design analysis based on an evaluation framework of requirements for ICT-enabled healthy lifestyle interventions.

2 Theory

The eSupported lifestyle program combines coach sessions with electronic dashboarding and self-management. Hybrid programs (face-to-face plus tele-support) have been indicated to be attractive (Demark-Wahnefried 2008) for participants because those participants have multiple preferences: face-to-face counselling is valued, but there are also perceived thresholds to face to face contacts due to travel- and logistics burdens for visiting a clinic. Hence follow-up contacts via telephone or internet are often preferred (Jones 2006). Finding the right mix between offline and online contacts is an ongoing design research challenge (Pekmezi 2011).

To increase solution impact, a hybrid or multi-channel service mix is recommended (Sperling 2009, Simons 2002, 2006, 2010, 2010b), combining electronic and face-to-face interactions. For example, face to face ‘on site’ coaching had as benefits: a richer service experience with the coach, with other participants and with a health focused ‘service scape’; group support experiences (obtaining additional social support and co-creating service experiences together); learning from each other; health experiences in healthy food-, sports- and relaxation exercises. Disadvantages are: more (travel) time needed; less flexibility regarding when and where; and not everyone likes group sessions (Demark-Wahnefried 2007). Electronic and (semi-)automated coaching has as benefits: more time-efficient; more flexibility in when and where to have contact; very explicit monitoring of your own progress online; having status reports including ‘next steps’ commitments always online. Disadvantages are: the sensory-, emotional- and group experiences are more limited. Also, the ‘service scape’ in which people are immersed is only virtual, not physical. In summary, often a hybrid service mix has most to offer.

In such a hybrid service mix, micro-learning tools accessible via smartphone, mail and/or web, potentially offer a number of advantages: they use a personal device that is available any time any place, they are efficient and can use idle time that is otherwise lost, and they are suited for just in time learning (Bruck 2012, Simons 2015).

Key functionalities to increase health motivations and behaviours in this eSupported lifestyle program are (Simons 2010 and 2014):

- A personal online health dashboard with graphs of progress towards adherence targets on the various health behaviours;
- Automated feedback (online and in email) on lifestyle aspects where relatively positive scores have been achieved (nutrition, physical activity, stress management or an overall score);
- (Tele)coaching by a health coach, generating online reports on progress towards adherence targets in the personal dashboard;
- The (tele)coaching sessions can be flexibly planned, based on convenience and participant preference: during in-clinic visits or phone based from home;
- Options to ask questions to the coach: via messaging within the dashboard or via email;
- Online schedule indicating upcoming events: group sessions, individual coach sessions (when and where), physical measurements, surveys;
- A micro-learning Health Quiz accessible via smartphone, mail and/or web;
- Reading materials in the mail;
- Weekly tips via email on health, motivation and self-management;
- Besides individual coaching, group sessions are also used in order to stimulate group support, mutual inspiration and encouragement, plus peer education.

Secondly, reviews (Jones 2006, Demark-Wahnefried 2008, Pekmezi 2011) of lifestyle interventions suggested that multidisciplinary interventions have advantages (diet, physical activity and mental health). There are health advantages, since the total health impacts are larger. And an important motivational benefit is that participants experience progress faster (Simons 2010), regarding quality of life and self-efficacy. This increases intrinsic motivation and chances of long term compliance (Seligman 2012, Baumeister 2011).

The lifestyle advice follows the guidelines of the Harvard Epidemiology and Nutrition Group for nutrition, physical activity and smoking cessation. Over the past decades, multiple studies from Harvard have illustrated that many diseases of affluence are largely preventable with only 5 or 6 healthy lifestyle guidelines. Willett (2004) repeats in an overview of these findings: 72% of colon cancer is preventable, 81% of coronary disease and 92% of diabetes type 2. The guidelines are (Willett 2004, 2011) to increase intake of fruits and vegetables (2,5 servings/day or more), to choose whole grains instead of refined grains, to have one daily serving of nuts and/or legumes, to limit intake of red meat and processed meat, to limit intake of trans and animal fats, and to have no more than 2 alcoholic beverages/day. Physical exercise guidelines are: 30 min/day moderate intensity activity (like walking or gardening) and 3x20 min/week intensive activity (Borg level 12-14). Stress management guidelines are: relaxation exercises for 30 min/day.

If we look at the design challenge of persuasive technology (Fogg 2002, 2009) for health, it was theorized and tested elsewhere that this challenge is not just located in the ICT design, but also in the design of the overall service scape, including health effects

and coach relationship (Simons 2014). It should generate positive, mutually reinforcing service experiences across communication channels and activate long term health motivation and -behaviours, in order to deliver long term results. This is reflected in the following design evaluation framework for health improvement ICT solutions (Simons 2014), see Figure 1. It helps evaluate the impact of ICT-enabled interventions on health effectiveness, coaching performance and ICT value adding.

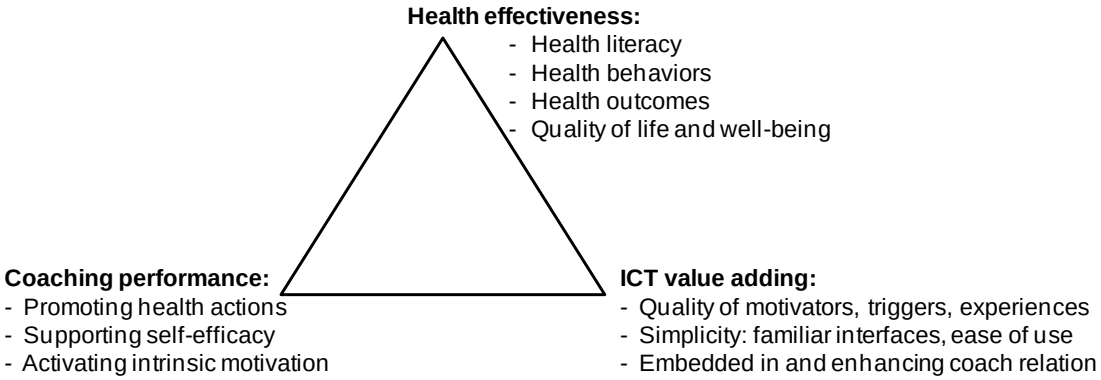

Figure 1: Basic requirements when designing ICT-supported healthy lifestyle interventions

Figure 1 addresses three evaluation domains. Firstly, health effectiveness not only includes health outcomes, but also health literacy ('as a user I know how to best serve my health'), health behaviours and health well-being (meaning health related quality of life (Ware 1998) and the Seligman (2012) dimensions of well-being related to health). Preferably, health interventions have broader and deeper impacts rather than narrow ones, since the former will improve health well-being more significantly. Experiencing larger health well-being impacts forms an important intrinsic motivator for health behaviours in the longer term. Secondly, coaching performance not only includes promoting health actions (improving health readiness by moving from awareness to intentions to behaviours as in the HAPA and i-change models, Schwarzer 2010, Wiedeman 2011), but also activating intrinsic motivations, and supporting users in their self-efficacy (their day-to-day attempts and successes to turn their health behaviour experiments into health wellness experiences, Lipke 2009). Thirdly, ICT value adding includes (Fogg 2002, Fogg 2009): value adding via high quality triggers, motivators and service experiences (which often involves using a mix of channels, each for their strengths – Demark-Wahnefried 2007, De Vries 2008, Sperling 2009, Simons 2004, Simons 2006), simplicity (which means using ICT interfaces that are mainstream for the user group and being very attentive to ease of use - many initiatives underperform due to usability barriers, see Jimison 2008) and finally: embedding applications in an overall health provider or coach relationship (so that the meaning is enhanced of the coach relationship as well as the meaning of the data). For example, the foundations of coaching include 'building rapport or relationship', using different levels of listening based on empathy and intuition, see Starr 2008. This is best done by a person. Whereas data capturing, processing and feedback to users is preferably automated (Simons 2010b).

3 Methods and Study Design

Our study consists of an RCT (Randomized Controlled Trial) within a larger employer vitality program. Participants were recruited in 2014, on a voluntary basis, from the employee base of the Delft University of Technology. Slightly more participants entered the program than required on the basis of the power calculations for minimal sample size.

After a 0-measurement of vitality and control variables and when meeting inclusion criteria, participants were randomly assigned to either a direct start of the lifestyle intervention (n=59), or to a waiting list with a start after a six weeks: the control group (n=57). Hence the control group consisted of participants who were re-measured six weeks later and then entered into the hybrid eHealth program.

The study protocol was approved by the medical ethics committee of Leiden University Medical Centre. The first measurements and randomization started in January, there were ten start groups during the year and the final (waiting list control) group started their eHealth support program on November 27th 2014. On January 13th 2015 they were the final group for which the 6-weeks post-start physical measurements were conducted. At the time of writing, their 3-months survey results were not available yet; for the other nine start groups they were.

Physical inclusion criteria were chosen on the basis of medical literature. The other in-/exclusion criteria were mainly concerned with feasibility and practicality: Can someone fully participate in the program and is there enough motivation? Eligibility following these criteria is checked by the company physicians, who know many of the employees. Besides, there are self-assessment questions in the 0-measurement for the prospective participants, regarding the degree of motivation and ability to participate.

The inclusion criteria are:

- Cardiovascular disease (including previous diagnoses, hypertension (>=140/90) or hypercholesteremia (cholesterol >= 6.0 or LDL >= 3.4), and/or diabetes-2 (including prediabetes risk: HbA1C >= 6.0) and/or being overweight (BMI >= 25);
- Physically, mentally and socially capable of participating in an intensive lifestyle program.

Exclusion criteria are:

- Serious comorbidity or treatment side effects that hamper participation;
- Psychiatric problems;
- Risk factor measurement outcomes which require immediate medication changes;
- Not enough motivation to participate (score < 3 ‘average’ on a 5-point scale).

In this employee sub-population with cardio-metabolic risk, standard deviation for total cholesterol and LDL cholesterol is about 0.9 mmol/l. Hence, power calculations indicated that if the true difference in the experimental and control means is 0.5 mmol/l, we needed to study at least 52 experimental subjects and 52 control subjects to be able

to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of the null hypothesis is 0.05.

Besides describing short term physical effects, a qualitative service design analysis is conducted in the results section, using the Figure 1 requirements framework from theory regarding the design of ICT-supported healthy lifestyle interventions.

4 Results

In this section we combine preliminary, short term results from the RCT measurements with a design analysis based on the framework of Figure 1 (from the Theory section). Table 1 shows the differences between the waiting list (control) groups and the intervention groups that had a direct eHealth support start.

Waiting list (control) participants (n=57):	***Direct start (intervention) participants (n=59):***
Descriptive: - Motivated volunteers. - Taken ownership by applying for study. - Physical measurements raised awareness. - Majority self-searched for measurement interpretation and started health actions.	**Descriptive: [as Waiting list, plus directly:]** - Intake & personal action plan. - Start workshop (full day) + coach sessions. - Health behaviour logging. - Coach progress logs in dashboard - Heath Quiz + weekly start tips.
Measurements: - Avg LDL reduction at 6 weeks waiting = ***0.08*** +/- 0.17 mmol/l (95% CI) (n=52) - Avg LDL reduction at 6 weeks post-start = ***0.16*** +/- 0.13 mmol/l (95% CI) (n=48) - Avg satisfaction start week = ***8.0*** (n=54) - Avg satisfaction 3 months = ***8.5*** (n=33*) - Avg recommendation 3 months = ***8.2*** (n=33*)	**Measurements:** - [pre-start difference is not in study design] - Avg LDL reduction at 6 weeks post-start = ***0.35*** +/- 0.16 mmol/l (95% CI) (n=53) - Avg satisfaction start week = ***8.2*** (n=55) - Avg satisfaction 3 months = ***8.6*** (n=46) - Avg recommendation 3 months = ***8.7*** (n=46)

Table 1: Comparison: Waiting list vs Direct start 6 weeks post-intervention start; *not all 3-month data available yet for Waiting list participants (CI= Confidence Interval; grades: 1-10)

The descriptive elements indicate that the waiting list participants do have incentives to start health improvements after initial measurements, even though they are on the waiting list. They were motivated to start health improvement, that had actively stepped forward and enlisted themselves for the study (a process involving significant obligatory paper work) and they had received the results of their physical examination. After the 6 weeks waiting period we had intakes with these participants, where the majority indicated that had tried to interpret the results (usually Internet aided) and started attempts at healthier behaviours. By comparison, the 'direct start' participants had similar incentives, plus the full hybrid eHealth support package.

Regarding physical measurements, the period of 6 weeks of waiting did not change LDL cholesterol (or any other health variables) significantly. By contrast, a direct start resulted in a 0.35 mmol/l LDL ('high risk') cholesterol reduction (significant, $p<0.05$), which is an improvement of about 10%. After delayed start (waiting list), LDL cholesterol reduced half that amount: 0.16 mmol/l (significant, $p<0.05$). Other health indicators also improved significantly ($p<0.05$) for the direct start group: BMI, total

cholesterol and diastolic blood pressure, but these variables have less statistical power to determine differences with the waiting list group, thus less suitable RCT endpoints.

For all n=116 participants, the average initial values were (no statistical differences between groups): LDL = 3.7 mmol/l, total cholesterol = 5.7 mmol/l, BMI = 27, blood pressure = 127/82 mm Hg, with medication aid for some participants. Reductions in medication did take place, but not in the first 6 weeks of the intervention. Finally, Table 1 shows somewhat lower satisfaction scores for the waiting list participants (not statistically significant), and especially a lower score in the recommendation intention after 3 months. For the direct start participants the recommendation score is relatively high, at 8.7 (10-point scale) The 95% Confidence Interval was 0.29 (n=46), but we cannot conclude on statistical significance of the difference with the 8.2 waiting list group recommendation, given the still low n=33 of these preliminary data. However, these grade differences do reflect the comments we heard during intakes and coach sessions: that several participants had lost part of their motivation or worked hard at the wrong things during the waiting list period.

Health Effectiveness	**Coaching Performance**	**ICT Value Adding**
Health Literacy: ++ Health Quiz and start tips. - Waiting list effect: self-search confusions. *Health behaviours:* - Waiting list effect: some taking the wrong actions. *Health outcomes:* - - Waiting list: poor short term effects. *Quality of Life:* + Participants sent thank you mails replying to the start tips.	*Promoting health actions:* + Suggestions in Health Quiz. - Waiting list: Some started in-effective behaviour patterns. *Supporting self-efficacy:* + Health Quiz: improved portfolio of strategies (coping, avoiding pitfalls) *Activating intrinsic motivation:* + Start tips: 24 weeks motivators on all health topics. - - Waiting list effect: Part of the start-motivation is gone.	*Motivators, triggers, experience*: + + Health quiz, start tips: (fun) experiences, triggers, hope, success experiences. *Simplicity:* +/- Old behaviour logging was a burden (limited adoption); the new version was better. *Fit with coach processes:* + Health Quiz enhances coach insights and suggestions. + The new behaviour logging enhances behaviour insights.

Table 2: Design evaluation on design requirements from Figure 1 (authors' opinions, 5-point scale from - - to ++)

Table 6 shows a qualitative design evaluation of effects observed by the authors during the 2014 RCT. On the one hand, several elements of eHealth support were added or changed, which led to improvements. On the other hand, there was a waiting list effect on several of our design requirements from Figure 1, which hampered performance on the design requirements.

There were three forms of eHealth support added. Two at the start of 2014. First, a selection of 24 weekly start tips in the mail, to support growth in health awareness and competences. Second, a micro-learning Health Quiz starting one month after the initial workshop. An initial service design description in given in Simons (2014, 2015). In the 2014 implementation we added gaming elements (points for trying, extra points for correct answers, speed points for fast responses, for completing a level and reaching daily targets) and team play (team scores and top score lists), plus further simplification of the user process (participants automatically receive daily, clickable emails to enable

answering Health questions; and weekly group progress statistics are mailed). A third improvement that was introduced at the end of 2014 was a simplified system for logging weekly health behaviours. So the final starting groups of 2014 benefitted from them and we could compare before-after differences.

In summary, in terms of design requirements, the largest hampering effects from the waiting list procedure were: on average a decay in motivation of participants, self-search for measurement interpretation abounded but led to confusion and to adoption of some poor quality health beliefs, plus several participants started in-effective or unhealthy behaviour patterns. Also the waiting list led to lower health outcome improvements: not just after the first six weeks of waiting, but also after six weeks of hybrid eHealth support.

The largest contributions from the Health Quiz were: improved health literacy and providing a continuous stream of motivators, triggers and success experiences (this enhances self-efficacy and further learning). The largest contribution from the 24 weekly start tips in the mail were: continued motivation support and providing triggers. The largest contributions from the improved weekly behaviour logging interface that started late in the year, from Dec 2014, are threefold. First, lower thresholds to logging (participants indicate that the new logging software is more enjoyable). Second, when people log a week's behaviour, they enter about 50% more entries (exercise, mental balance, buddy contacts and foods/drinks). Third, participants look more closely at the progress graphs, which we contribute to freeing up extra mental processing capacity.

5 Discussion and Conclusion

This preliminary analysis has several limitations. First, the 3 months survey data is not complete yet: due to the late starting date of the final group their 3 months data was not be available at the time of writing. Second, the study design for the RCT was aimed at testing eHealth intervention effects on physical risk parameters after 6 weeks. The design analysis was a qualitative addition to that study design. Third, regarding external validity, these study results may only apply to motivated individuals, who volunteer for lifestyle training. Four, thanks to the fact that the control group also entered the program, but after 6 weeks waiting list, we expected a limited 'demotivation' effect of being randomized into a control group. Still, some demotivation was observed, but not quantified.

Still, on the positive side this study design did provide an opportunity to observe waiting list effects and to conduct a design analysis in relation to a number of eSupport changes that were made. Further details are provided in the remainder of this paper for specific situations.

5.1 Design Lessons and Implications for Practice

Many employers offer (preventive) medical checkups, often without explicit follow up programs for health support. We have observed in the waiting list group, that a majority of people use the Internet and/or family/friends for: a) interpretation and b) possible health behaviour improvements. Unfortunately, this regularly leads to confusion and/or ineffective behaviours. Which partly explains why the waiting list results in our study

were minimal. Moreover, even just a 6-weeks-ineffectiveness period was enough to reduce about half of the positive risk factor effects of our hybrid eHealth support after participants did start program, at least in the short term (6 weeks after start). This suggests that offering employees active health support directly after measurements yields better results. We have to wait for the 1-year results to determine the longer term risk factor impacts.

A second intervention design lesson also regards timing. In our 2014 RCT, we started our micro-learning Health Quiz plus weekly start tip mails only after 1 month, based on the rationale that the first intervention month is already packed with many support interactions (individual and group sessions, surveys, measurements, supporting materials) and we wanted to limit the work load. However, we observed that the start workshop is such a trigger for heightened motivation, health interests, health plans and a desire to learn more (see also the previous design lesson), that it seemed logical to start the Health Quiz and start tips mails directly. This was implemented in 2015 and the first (very preliminary) results do point to faster micro-learning Health Quiz course progression.

Finally, logging health behaviours is very often perceived as a burden (Simons 2012, 2013) even though it may improve health behaviour self-awareness and insights. During the second half of 2014 an improved interface was developed for logging weekly health behaviours (physical activity, mental energy, buddy system and diet). In January 2015 it went 'live' and several groups experienced the improvements in comparison to the old interface. The extra uptake (see section 4 Results) and increased 'mental space' for learning effects instead of logging efforts, do confirm the 'persuasive technology' theories of limiting burdens as much as possible and the eagerness of people to grow and develop (Fogg 2002, 2009).

5.2 Implications for Theory

The health support theory that suggests to start health improvement at the peak of motivation (Stull 2007) was confirmed in the sense that waiting list participants did not manage to catch up with the direct start participants in the short term (6 weeks after intervention start). They appear to have missed the opportunity to use their initial motivation. We have to wait for the long term results to know if this difference disappears in the longer run.

Another interesting point, is the question what increases intrinsic motivation and helps to exploit it. When there is a health crisis (cancer or other diagnosis) this raises motivation and a majority of patients start implementing one or more health behaviour changes (Stull 2007). This is a negative (and unplanned) event that raises the sense of urgency. However, the hybrid eHealth support program appears to offer a more positive and more planned increase in intrinsic motivation and self-efficacy (Bandura 1997): that it pays rapid dividends to live more healthily. We believe this is an interesting erea for further research of increasing health self-management competences (Simons 2015) via training and positive reinforcement, following the theories of positive psychology (Seligman 2012) and 'automatic' healthy choices, perceptions, behaviours and self-assessments (Kahneman 2011). This appears to create a positive spiral of: increased

awareness, effective behaviour experiments, increased quality of life and health results, increased competence, increased motivation, eagerness to learn more, and so on.

In summary, we can conclude a few key points from our study. First, the hybrid eHealth intervention did significantly improve physical risk factor variables after 6 weeks, and that motivation and measurement alone (waiting list) do not. Second, the timing of the start does matter. Theory that suggests to start health improvement at the peak of motivation (Stull 2007) was confirmed in the sense that waiting list participants did not manage to catch up with the direct start participants in the short term (6 weeks after intervention start). This suggests that offering employees active health support directly after physical measurements (health check-ups) is more effective for improving health than the common practice of focusing on the employee check-up itself.

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