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Feasibility of a web-based randomised controlled trial for a tailored physical activity intervention

Abstract

active-online.ch is a freely available Internet-based physical activity counselling programme disseminated population-wide with a multimedia strategy. The feasibility of an Internet-based randomised controlled trial was tested in a small-scale study. Participants were recruited using print advertisements, Internet banners and e-mail messages. After baseline assessment, they were randomised to the intervention programme active-online.ch or a control website. Participants were re-contacted by e-mail after six weeks and six months for follow-up assessment. E-mail invitations in an administration unit and a print advertisement were most effective for recruitment. After six weeks, complete data was available from 76% of the original participants, after six month from 63%. 48% of the original subjects were women, 76% between 30 and 60 years old and 57% insufficiently active. At every stage of the study, the proportion of women in the trial decreased significantly. 35% of the participants in the intervention group completed the intervention programme. For future full-scale randomised trials using an Internet design, recruitment should be planned in view of the implementation strategy of the intervention. Expected adherence to both the study protocol and the physical activity intervention need to be considered when sample sizes are estimated.

Zusammenfassung

active-online.ch ist ein Internet-basiertes Motivationsprogramm für mehr Bewegung, welches gratis zur Verfügung steht und mit einer Multimedia-Strategie bevölkerungsweit implementiert wird. Die Machbarkeit einer Internet-basierten randomisierten kontrollierten Studie wurde in kleinem Massstab getestet. Die Teilnehmer wurden über Inserate in Printmedien, Internetbanner und E-mail-Aufrufe rekrutiert. Nach der Baseline-Befragung wurden sie zufällig entweder dem Interventionsprogramm active-online.ch oder einer Kontrollwebsite zugewiesen. Die Teilnehmer wurden nach sechs Wochen und sechs Monaten per E-mail für die Nachbefragungen eingeladen. E-mail-Aufrufe in einer Verwaltungseinheit und ein Printinserat waren die effizientesten Rekrutierungskanäle. Nach sechs Wochen lagen von 76%, nach sechs Monaten von 63% der Teilnehmer vollständige Daten vor. Bei Studienbeginn waren 48% der Teilnehmer Frauen, 76% waren zwischen 30 und 60 Jahre alt und 57% waren ungenügend aktiv. In allen Phasen der Studie nahm der Frauenanteil signifikant ab. 35% der Teilnehmer in der Interventionsgruppe absolvierten das vollständige Interventionsprogramm. Bei zukünftigen Internet-basierten randomisierten kontrollierten Studien sollte sich die Rekrutierung der Teilnehmer an der Strategie zur Umsetzung des Interventionsprogramms orientieren. Ferner müssen für die Abschätzung der Grösse des Studienkollektivs sowohl die zu erwartende Einhaltung des Studienprotokolls als auch die Nutzung der Intervention berücksichtigt werden.

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Introduction

The importance of physical activity as a health resource and for the prevention of various chronic diseases has been documented extensively (USDHHS 2008). Nevertheless, almost two thirds of the Swiss adult population do not meet the current recommendations for health-enhancing physical activity (Lamprecht and Stamm, 2006). Therefore, the need for effective physical activity interventions is clearly given.

active-online.ch is an intervention programme developed between 1999 and 2003 in Switzerland. The freely available interactive website offers an individually tailored counselling and motivation programme for health enhancing physical activity. The programme is available in German, French and Italian, its target population are physically inactive or insufficiently active adults between about 30 and 60 years of age. The programme simulates an individual counselling situation by delivering instant feedback on the users' motivational situation and behavioural characteristics assessed by tailoring questionnaires. The tailoring is based on the Transtheoretical Model of behaviour change (Prochaska et al., 1992).

In active-online.ch, participants fill in one to four tailoring-questionnaires to assess their current stage of change, the pros and cons for change, self-efficacy, and the use of processes of change. After each tailoring-questionnaire, a motivational feedback tailored to the individual characteristics is displayed. Completely inactive participants are motivated to start with any moderate intensity physical activity. Depending on their preferences, occasionally active persons are motivated either for regular moderate intensity or for regular vigorous intensity activities (Martin-Diener et al., 2004). The programme can be used anonymously. However, users registering their e-mail address receive e-mail reminders to revisit

active-online.ch. If they do so, they can get an individually tailored feedback on their changes since the last visit.

A previous process evaluation in the German speaking part of Switzerland demonstrated that active-online.ch reached its target population and that the structure and design of the website were well accepted (Martin-Diener and Thüring, 2001). The programme was officially launched in April 2003 and then disseminated population-wide in a multimedia strategy. Between April 2003 and April 2008, more than 250 000 visits were counted on the homepage and some 100 000 counselling sessions were registered in the active-online.ch database.

Evidence about the effectiveness of screen- or web-based physical activity intervention programmes is limited. There are two reviews so far investigating the effectiveness of website-delivered physical activity interventions. It was summarised that a little more than half of the controlled trials reported positive behavioural outcomes (Vandelanotte et al., 2007) and that there is evidence that interventions were more effective than a waiting-list control strategy (van den Berg et al., 2007). Most of the studies included in these reviews were conducted in highly controlled settings such as supervised computer labs. There is a clear lack of studies investigating the effectiveness of web-based interventions in open settings.

The present study was conducted to explore whether an open Internet-based intervention study design can be used to assess the effectiveness of the web-based intervention active-online.ch. In order to be able to plan a full-scale randomised controlled trial, the following research questions were to be answered: How many participants can be recruited with a multimedia strategy and how cost-effective are the different recruitment channels? How many participants are lost during the different stages of the study? What are the characteristics of the self-selected participants at the different stages of the study and are they comparable to spontaneous users of active-online.ch? How intensively do the participants randomised to the intervention group use the intervention programme?

Methods

Communication channels similar to the ones used in the multimedia communication strategy of active-online.ch were used to recruit participants for an "online health study" conducted by the University of Zurich *(see table 1)*. In a first phase, a 7×3 cm advertisement was placed once in a Swiss Sunday newspaper ("Sonntagsblick") and once in another weekly magazine ("Brückenbauer"). A banner was placed in the lifestyle section of the biggest Swiss Internet portal "Bluewin" for one full Sunday in the lifestyle section and on the Portal "Swissonline" for three consecutive days from 17.00 to 22.00 hours. For ten weeks, a link was placed on the homepage of the online version of the weekly print magazine "Beobachter". In a second phase, 277 employees of a unit of the Swiss Federal administration were invited by e-mail from their management to participate in the study.

With the participants recruited for the study, a small-scale web-based randomised controlled trial was carried out as it would be with bigger sample sizes in order to compare the effectiveness of active-online.ch with no physical activity intervention. Data was collected between February and July 2003. The study language was German.

Participants were invited to go to www.onlinestudie.ch. This website was independent from active-online.ch and served for randomisation and questionnaire administration *(see figure 1)*.

Participants answered the online baseline questionnaire with questions on recruitment channel, socio-demographic characteristics (gender, age, living situation and education) height, weight, smoking habits, subjective health and physical activity behaviour. Then they registered their e-mail address and they were randomly assigned (Steinhausen, 1993) to either the physical activity promotion programme active-online.ch (intervention group) or to an interactive programme on sun protective behaviour (control group).

The participants in the control group were forwarded to the website www.sunattack.ch, which was provided by the Swiss Cancer League in collaboration with other partners. The site offered an interactive part where visitors could learn about their skin type and the respective appropriate sun-protective measures. No registration to the control website was possible.

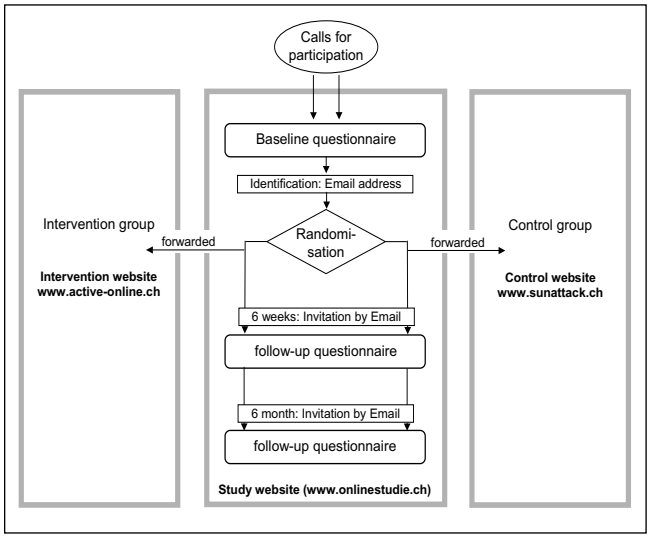

Figure 1: Study design and protocol

E-mail addresses were used to identify participants and to detect multiple registrations of the same person. After six weeks and after six months, participants were invited by e-mail to answer the follow-up questionnaires on the study website. After six weeks, they were given questions on smoking habits, subjective health and physical activity behaviour. After six months, in addition they were asked to rate on a five-point scale how time-consuming participation in the study had been.

During the first phase of participants' recruitment, the physical activity readiness questionnaire PAR-Q (ACSM and AHA, 1998) was an integral part of the baseline questionnaire. However, too many participants were excluded from the study after indicating at least one positive answer in the PAR-Q. So for the second phase of recruitment, the PAR-Q was only available as an optional element of the intervention active-online.ch in the same way as it is in routine use.

To test group differences, χ^2 tests (Pearson) were used for nominal data and t-tests were used for means. Odds ratios were calculated to assess the magnitude of group differences in 2x2-tables. Statistical analyses were performed using SPSS 10 for Windows. 95% confidence intervals for frequencies were computed using the software Epi Info 2002.

Results

Recruitment

Between February and July 2003, 1911 visits were counted on the study homepage. 321 participants completed the baseline questionnaire (49.2% females), 303 individuals (47.7% females) gave their e-mail address and were thus ready to participate in the study.

Of those 303 individuals who were ready to participate, 35.3% were recruited by e-mail, 26.4% by the print advertisements, 20.1% by the link on the website of the online version of a print magazine, 12.6% by the Internet banners and 5.6% by other channels (e.g. information of a friend or finding the website by chance while surfing). While the proportion of men and women who participated due to the e-mail recruitment was almost equal, more women (62.7%) than men responded to the other media calls. The link on the homepage of the print magazine as well as the recruitment by e-mail did not cause any direct costs. The cost-effectiveness of the other recruitment channels is displayed in *table 1.*

	Recruited individuals ready to participate [a]	Costs of publication	Costs per recruited individual ready to participate [b]	Participants included in the trial	Response at follow-up (% of participants included in the trial)
Internet banner "Bluewin"	26	666.–	26.–	11	63.6
Internet banner "Swissonline"	12	417.–	35.–	2	50.0
Print advertisement "Sonntagsblick"	68	934.–	14.–	24	70.8
Print advertisement "Brückenbauer"	12	788.–	66.–	2	100
Link on online version of the "Beobachter" magazine	61	0.–	0.–	18	66.7
E-mail messaging	107	0.–	0.–	107	81.9
Other	17	0.–	0.–	7	55.6

[a] including individuals excluded due to a positive answer in the PAR-Q
[b] baseline questionnaire completed and e-mail-address available

Table 1: Cost-effectiveness of the recruitment channels (in Euro) and response after six weeks depending on the recruitment channel

Participation

Figure 2 illustrates participation and the reasons for loss to follow-up in the different phases of the randomised controlled trial. 62.0% of the participants recruited by the media calls were excluded from the study automatically because of at least one positive answer in the PAR-Q (ACSM and AHA, 1998). Thus, 171 participants could be randomised to either active-online.ch or the control intervention. Complete data from baseline and the first follow-up after six weeks were available from 76.0% of the participants, complete data from all three measurements from 62.6%. Nine participants responded after six months but had not done so after six weeks. The response depending on the recruitment channel is displayed in *table 1*.

After six months, 41.1% of the participants rated the amount of time they had invested in the study as just right, 53.3% as little or very little. Six participants (5.6%) thought their invested time was much or too much. No differences were found between the intervention and the control group, even though the intervention programme was more time-consuming than the control programme.

Description of participants

Among the 303 individuals ready to participate in the study, 47.7% were females and 75.9% were between 30 and 60 years old. The other characteristics of these participants and of those 18 subjects who were reluctant to give their e-mail address are displayed in *table 2*. The latter were significantly more often women (OR = 3.84, p <0.05, CI 1.17–16.32), married or living in a partnership (OR = 7.53, p <0.05, CI 1.14–318.0) and reported significantly better subjective health (OR = 4.76, p <0.01, CI 1.53-17.44) than the individuals ready to participate.

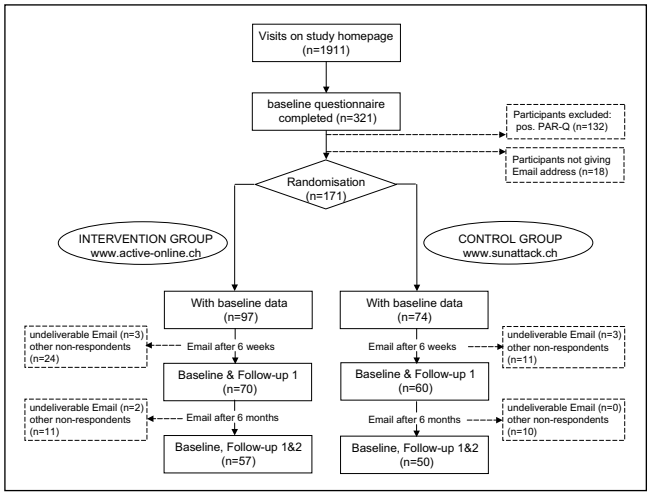

Figure 2: Recruitment and participation at follow-up 1 and 2

The mean age of the 171 participants finally included in the trial was 42.2 years (SD = 11.5). 33.3% were women, 69.6% were married or lived in a partnership, 49.7% had children living with them. 24% were smokers, 33.9% had a BMI > 25kg/m2 and 55.6% were not sufficiently physically active. 43.9% reported their subjective health as very good or excellent. There were no differences between intervention and control group.

Table 3 shows the characteristics of participants in the trial who responded after six weeks and of those individuals who did not respond. Non-respondents after six weeks were significantly more often women (OR = 2.09, p <0.05, CI 0.95–4.56) and smokers (OR = 2.69, p <0.01, CI 1.15–6.14). At baseline, respondents and non-respondents had not differed regarding physical activity behaviour.

Use of the intervention

The analysis of the database of active-online.ch allowed to get an overview of how intensively the individuals randomised to the intervention group had actually used the intervention: 70.1% had started to answer the first tailoring questionnaire of the intervention programme. About two thirds of those participants not starting the intervention programme were not able to do so because their Internet security software prevented them from being forwarded to the intervention website. 52.6% of all 97 participants in the intervention group completed at least the first tailoring questionnaire and received a first feedback on their current stage of change. 35.0% of the participants in the intervention group completed all tailoring questionnaires and received all possible feedbacks.

Discussion

The aim of this study was to test the feasibility of a web-based randomised controlled trial and to gain knowledge necessary for the planning of a full-scale effectiveness study of active-online.ch. In order to meet the explorative character of this study, the discussion of the results is structured by the main research questions.

It was possible to recruit participants through a variety of measures and estimates of the "yield" to be expected in a country like Switzerland could be derived. The most effective method to recruit participants was the e-mailing to employees of a Federal

	Individuals recruited at baseline ready to participate (n = 303, except n = 184 for education) [a]	Individuals recruited at baseline not giving e-mail address (n = 18, except n = 6 for education) [a]	p
Females (%)	47.7 (41.8–53.3)	77.8 (52.4–93.6)	**.014**
Mean age	42.4 (41.0–43.8)	39.4 (34.0–44.9)	.317
Living situation (%)			
married/partnership	69.6 (64.1–74.8)	94.4 (72.7–99.9)	**.044**
with children	50.8 (45.0–56.6)	50.0 (26.0–74.0)	.968
Lower educational level [b] (%)	28.3 (21.9–35.4)	11.1 (4.3–77.7)	.786
Current smokers (%)	27.4 (22.5–32.8)	33.3 (13.3–59.0)	.584
BMI >25 (%)	35.3 (30.0–41.0)	27.8 (9.7–53.5)	.515
Not sufficiently active [c] (%)	57.4 (51.6–63.1)	44.4 (21.5–69.2)	.280
and intention to become more active (%)	41.3 (35.7–47.0)	22.2 (6.4–47.6)	.110
and no intention to become more active (%)	15.8 (12.0–20.6)	22.2 (6.4–47.6)	.475
Subjective health very good or excellent (%)	35.3 (30.0–41.0)	72.2 (46.5–90.3)	**.002**

[a] due to a technical problem, the question on education had not been included in the baseline questionnaire at the beginning of the trial.
[b] compulsory school or vocational training.
[c] not practising half an hour of at least moderate intensity physical activity on five or more days of the week and not practising 20 minutes of vigorous intensity physical activity on three or more days of the week

Table 2: Characteristics of the participants recruited at baseline who were willing to participate and those who quit prematurely (t-test for mean age; χ^2-test for all other comparisons; 95% confidence intervals in brackets).

	Respondents at follow-up (n = 130 except n = 129 for education [a])	Non-respondents at follow-up (n = 41 except n = 23 for education [a])	p
Females (%)	29.2 (21.6–37.8)	46.3 (30.7–62.6)	**.043**
Mean age	42.2 (40.2–44.0)	42.2 (38.0–46.5)	.947
Living situation (%)			
married/partnership	70.8 (62.2–78.4)	65.9 (49.4–79.9)	.626
with children	52.3 (43.4–61.1)	41.5 (26.3–57.9)	.385
Lower educational level [b] (%)	23.3 (16.3–31.5)	39.1 (19.7–61.5)	.108
Current smokers (%)	19.2 (12.8–27.1)	39.0 (24.2–55.5)	**.010**
BMI >25 (%)	33.8 (25.8–42.7)	34.1 (20.1–50.6)	.972
Not sufficiently active [c] (%)	56.2 (47.2–64.8)	53.7 (37.4–69.3)	.779
and intention to become more active (%)	37.7 (29.3–46.6)	39.0 (24.2–55.5)	.878
and no intention to become more active (%)	18.5 (12.2–26.2)	14.6 (5.6–29.2)	.574
Subjective health very good or excellent (%)	41.5 (33.0–50.5)	51.2 (35.1–67.1)	.276

[a] due to a technical problem, the question on education had not been included in the baseline questionnaire at the beginning of the trial.
[b] compulsory school or vocational training.
[c] not practising half an hour of at least moderate intensity physical activity on five or more days of the week and not practising 20 minutes of vigorous intensity physical activity on three or more days of the week.

Table 3: Characteristics of the participants in the trial: comparison of respondents and non-respondents after six weeks (t-test for mean age; χ^2-test for all other comparisons; 95% confidence intervals in brackets).

Administration unit. The fact that a member of the top management sent the e-mail and invited the employees to participate has probably contributed to this high participation. Despite its very small size, the print advertisement in a weekly Sunday newspaper was a relatively effective and cost-effective way to recruit participants. While 39.0% of the contacted federal employees responded to the e-mail call, it was estimated from the official circulation of the print magazines that about 0.03‰ of their potential readers responded to the advertisements. A substantial number of participants could be recruited by the link on the homepage of the online version of a biweekly print magazine. This number resulted despite the fact that less than one participant per day was recruited, because the button was online during 10 weeks for free. The Internet banners were neither cost-effective nor a successful way of recruiting a large number of participants, although the clicking rate on them was not lower than for comparable commercial banners according to the marketing departments of the two websites.

About one sixth of all individuals visiting the study website completed the baseline questionnaire, only 5.6% of them refused to register with their e-mail address. Once the participants entered the study, complete data from three assessments was available from almost two thirds of them. Only few undeliverable e-mails were encountered, the main reason were probably misspellings. The fact that 5.3% of all participants in the trial responded after six months but not after six weeks suggests that in a full scale study it should be considered to re-contact non-respondents in order to increase response. In the original design of the study, a vast proportion of participants was excluded because of a positive answer in the PAR-Q (ACSM and AHA, 1998). It was concluded that the use of the instrument without any further context information or instructions would lead to extremely high sensitivity and low specificity. The decision to include the PAR-Q only as an optional element in the intervention website was further supported by the fact that individuals with a positive PAR-Q did not differ from those with

a negative one regarding age, living situation, education, smoking status, BMI, physical activity behaviour and intention to increase physical activity.

Regarding gender and age, the self-selected study participants seemed to be comparable to the spontaneous users of active-online.ch. In a first evaluation period in January 2001 (Martin-Diener and Thüring, 2001), 59.3% had been males and 75.0% had been between 30 and 60 years old. Education is not assessed in the programme active-online.ch, therefore it is not possible to compare the educational level of the individuals recruited for our study with the level of those visiting active-online.ch spontaneously. The proportion of insufficiently active individuals was higher in our study than among the users of the first evaluation period (38.6%). This might be the case because the study had been announced as a "health study", whereas the media in the evaluation period of active-online.ch had introduced a "physical activity programme". At every stage of the study, the proportion of women in the study decreased significantly. This repeated differential dropout of women could not be explained after further analysis of the data. Regarding other characteristics, differential dropout occurred only at single stages and not repeatedly.

In the study presented here, it was decided to recruit for a "health study" because of the better chance of reaching physically inactive people and the control group was exposed to a website on sun-protective behaviour which has no obvious link with physical activity behaviour. An alternative approach would have been to recruit for a physical activity study and to expose the control group to a standard physical activity intervention.

Despite the fact that only very few participants reported that the study took too much of their time, only one third completed all tailoring questionnaires of the intervention programme. These proportions have to be kept in mind when estimating expected outcomes in intervention studies. In addition, technical limitations such as the ones caused by security systems and spam filters have to be identified and specific solutions must be developed.

Important experiences have been made for the development of a full-scale randomised controlled trial using an open-access Internet design. Possibilities for recruitment of participants have been described in a way that allows cost estimates for study budgets. For the design of future effectiveness studies, the choice of the control group should be considered in view of the implementation strategy for the intervention under study and the contrast of interest.

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