Effectiveness of an online self-help program for people who have completed cardiac rehabilitation in the Netherlands, Germany and China.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27680

Source
NTR

Brief title
RENATA

Health condition

Cardiovascular diseases, fruit consumption, vegetable consumption, physical activity

Sponsors and support

Primary sponsor: Jacobs University Bremen gGmbH
Campus Ring 1
28759 Bremen
Germany
Source(s) of monetary or material Support: Wilhelm-Stiftung für Rehabilitationsforschung (Germany)

Intervention

Outcome measures

Primary outcome

The primary goal of this study is to analyze the effectiveness of a rehabilitation aftercare program with regard to the level of physical activity and nutrition.

Secondary outcome

The primary goal of this study is to analyze the effectiveness of a rehabilitation aftercare program with regard to the level of physical activity and nutrition. Other study parameters which will be considered are demographic variables, stage, SES, age, gender, depression, family status, nationality and diseases.

Study description

Background summary

Cardiac rehabilitation is a central part in the recovery process. Health behavior change is an important issue within rehabilitation and patients have to learn how to improve their eating habits and increase their physical activity. Back home, the adoption, maintenance and transfer into daily life of the behavior change is difficult. This may have negative consequences for the health status of those people. An internet-based rehabilitation aftercare program could support the adoption and maintenance of a healthier lifestyle to increase wellbeing and recovery from the medical incident or the chronic condition. Using computer-based interventions; patients are able to follow the aftercare program at home, with a flexible time regime which they can adapt to their needs.
The study will be conducted in the Netherlands, Germany and China and aims at improving self- management skills to maintain the behavior change learned during the rehabilitation and transfer them into their daily life after rehabilitation.

Study objective

Cardiac rehabilitation is a central part in the recovery process. Health behavior change is an important issue within rehabilitation and patients have to learn how to improve their eating habits and increase their physical activity. Back home, the adoption, maintenance and transfer into daily life of the behavior change is difficult. This may have negative consequences for the health status of those people. An internet-based rehabilitation aftercare program could support the adoption and maintenance of a healthier lifestyle to increase wellbeing and recovery from the medical incident or the chronic condition. Using computer-based interventions; patients are able to follow the aftercare program at home, with a flexible time regime which they can adapt to their needs. This project aims at improving self-management skills to maintain the behavior change learned during the rehabilitation and

transfer them into their daily life after rehab.

Objectives:

1. Testing the effectiveness of an internet-based intervention with tailored feedback: are the participants in the intervention group able to adopt and maintain a healthy lifestyle with regard to physical activity (PA) and fruit and vegetable (F&V) consumption?

2. Modification of complex behaviors: What is the effectiveness of three different intervention groups (simultaneous vs. sequential behavior change) compared with each other and with a waiting-list control group, and which mechanisms can be observed?

3. International comparison: is the intervention provided in Germany, the Netherlands and China equally helpful or is there any country specific difference observable?

4. Age effects: to what extent does an age-specific difference in the effectiveness of the intervention transpire?

Study design

Study time points:

1. April 2012: Study start, intervention and questionnaire development;

2. October 2012: Coding intervention;

3. April 2013: T0, implementation intervention T1 and T2;

4. July 2013: Implementation T3;

5. October 2013: Implementation T4;

6. January 2014: Implementation T5;

7. April 2014 – March 2015 : Evaluation intervention effects.

The interventions has five measurement time points: The data base consists of participant related variables which are collected at the beginning of the rehabilitation (T0). At the beginning of the aftercare program (T1) participants will answer the baseline questionnaire and then follow up measurements will follow: at the program end (T2), after four weeks (T3), six months (T4) and 12 months (T5) after the program has been completed.

Intervention

The online based intervention will be divided into 3 intervention groups (IG I-III) and one waiting control group. A computer program will randomly group the participants into one of the intervention group (IG I-III) or into the control group:

1. IG I: sequential – first physical activity (PA) then fruit and vegetable (F&V) consumption;

2. IG II: sequential – first F&V consumption then PA;

3. IG III: synchronous – PA and F&V consumption.

The waiting-list control group does not participate in any support program during the intervention period. After the completion of the second measurement (approx. 4 weeks after the end of the intervention and participating at T3), the control group participants receive access to the e-learning program (= waiting control group design).

Each of the three intervention groups (IG I-III) receives an eight week lasting, weekly support program. It is an theory based individual e-learning aftercare program. Participants will be asked to visit the online program once a week. Each session will take approximately 15 minutes. During the intervention sessions the main focus lies on the formulating of own health behavior goals with regard to PA and F & V consumption. During each session participants will receive personalized feedback which is based on the baseline questionnaire and on the information they give during the sessions.

The intervention contains work tasks, assignments, model learning to increase self-efficacy, information pages to increase risk perception and positive outcome expectancies, guidelines to formulate action plans to support the translation of intentions into behavior and guidelines to formulate coping plans to handle obstacles.

In concrete terms, that means that during each intervention session another concept will be addressed. At the first session, participants will receive feedback and information about their risk perception and outcome expectancies. The next time participants will be asked to formulate own individual goals and specific plans with regard to PA and F&V intake. For example “I would like to go for a walk in the park for 30 minutes on Tuesday, Thursday and Saturday.” All plans have to be evaluated by self-reflection with regard to the feasibility and can be adjusted if they were ineffective. After the plans have been tested in practice, participants will be asked to identify their personal barriers and obstacles which hinder them to put their plans into practice. Again, these coping plans have to be evaluated by the participants and adjusted if necessary. The intervention will be enriched by different tools to make it easier to handle the plans like with the use of a personalized agendas in which an overview is given of the plans and respondents will receive different kinds of feedback to see their own progress. Furthermore, with the use of role models participants get example who to

formulate goals and plans.

The aftercare program will be given to each respondent addressing both target behaviors, but the order varies between intervention groups: In the first two intervention groups, the interventions will be carried out sequentially (IG-I: first physical activity, then nutrition; IG-II: first nutrition, then physical activity). Respondents participating in the third intervention group IG-III receive the intervention synchronously for both health behaviors.

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Eligibility criteria

Inclusion criteria

1. People aged 45-85 years;

2. People have Internet access;

3. People have sufficient knowledge of the Dutch/German/English/Mandarin language, writing and reading skills;

4. People have completed cardiac rehabilitation treatment;

5. People received behavior lifestyle recommendations with regard to physical activity and fruit and vegetable consumption.

Recruitment of the participants will be done within rehabilitation facilities; rehabilitation centers, policlinics and hospitals which offer cardiac rehabilitation.

Exclusion criteria

1. People who do not want to sign the informed consent;

2. People with contraindications with regard to physical activity and fruit and vegetable intake;

3. People younger than 45 years or older than 85 years;

4. People without Internet access;

5. People with insufficient abilities to use computer and Internet;

6. People with poor cognitive performances/ dementia.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2013

Enrollment:	2957
Type:	Anticipated

Ethics review

Positive opinion Date:	15-11-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3556
NTR-old	NTR3706
Other	METC Atrium-Orbis-Zuyd : 12-N-124
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A