INTRODUCTION
Many patients with different types of disabilities and chronic diseases do not obtain the recommended amount of physical activity (PA) that is required for maintaining health. To this end, these patients spend considerably more time in sedentary (sitting)
behaviour compared with the general population, especially those with neuromuscular disabilities and/or those who use a wheelchair for mobility. Knowing its health-enhancing effects such as the positive effects on mobility and quality of life for persons with a disability, a physically active lifestyle is strongly recommended for persons with a disability or chronic health conditions. Consequently, the promotion of PA behaviour among those persons is of utmost importance. A potentially effective intervention to stimulate long-term participation in PA and sports in persons with a disability or chronic disease is tailored counselling. An intervention that starts during rehabilitation and continues during the transfer to the home setting and also in engaging in PA and sports (ie, physical, social, attitudinal and financial challenges and barriers) an intervention that starts during rehabilitation and continues during the transfer to the home setting and the first months at home is perhaps even more effective. Such a three-phase intervention is expected to contribute in maintaining the level of PA in the home setting as acquired during rehabilitation and thereby is expected to prevent a postrehabilitation decline in PA and in turn may also counteract a postrehabilitation health decline. Furthermore, when using tailored counselling, such intervention meets the patients’ need of professional tailored support at discharge and follow-up, as evidenced by recent studies.

As far as known by the authors, only one study has examined the effects of such a three-phase intervention including tailored counselling and with the aim to stimulate PA behaviour after discharge from rehabilitation. The results from this randomised controlled trial (RCT) indicated that PA behaviour and sport participation were successfully improved up to 1 year after discharge in a heterogeneous inpatient and outpatient population. However, considerable variation in response was observed in the sense that some patients showed a relevant beneficial response while others showed no or only a small response on PA behaviour. This suggests that the effectiveness of such a programme probably differs between patients, like patients with different ages. Other factors that are possibly associated with the effectiveness of a tailored counselling programme could be patient’s characteristics (eg, diagnosis and stage of behavioural change) and characteristics of the programme (eg, total duration of consultations, extent to which Motivational Interviewing (MI) is applied and treatment form under which the programme is offered).

Given the promising results of a three-phase counselling intervention including tailored counselling, the next step is now to identify factors that may explain the differences in patients’ PA behaviour after programme completion. Insight into these factors will contribute to better understand why different patients who all participated in the same programme show different changes in PA behaviour over time. In addition, insight into these factors will help to develop more effective programmes with the aim of stimulating PA behaviour after discharge from rehabilitation, and to offer those programmes in a more efficient way.

A longitudinal cohort study is considered to be an appropriate design to complement the previous RCT study and to perform more in-depth analyses with the aim to identify those explanatory factors. The ‘Rehabilitation, Sports and Active lifestyle’ study (ReSpAct study; http://www.respact.nl/en) is a nationwide longitudinal cohort study that evaluates the PA and sport stimulation programme ‘Rehabilitation, Sports and Exercise’ (RSE). This programme is based on the evidence-based programme of van der Ploeg and is characterised by both the three-phase intervention set-up and the use of tailored counselling. Since 2012, the RSE programme is being implemented in 18 rehabilitation centres and departments of rehabilitation in general hospitals in The Netherlands and is offered to persons with a variety of physical disabilities and chronic diseases.

The current paper presents the study design of the in-depth scientific evaluation of the RSE programme among patients with a physical disability and/or chronic disease in Dutch rehabilitation care. The main aims of this study at patient level are to gain more insight into patients’ PA behaviour and into factors that may help explain differences in patients’ PA behaviour after programme completion and at follow-up. For this purpose, both programme outcomes and potential explanatory factors (ie, patient and programme characteristics) are being assessed.

METHODS AND ANALYSIS

Study design

The ReSpAct study is a multicentre longitudinal cohort study that is designed to scientifically evaluate the RSE programme. Since 2012, the RSE programme is being implemented and executed within 12 rehabilitation centres and 6 departments of rehabilitation in general hospitals in The Netherlands. Simultaneously, the ReSpAct study is being conducted within these same 18 rehabilitation institutions.

The different subprojects of the ReSpAct study (figure 1) focus on the evaluation of the RSE programme at patient level, the process evaluation of the implementation of the RSE programme within Dutch rehabilitation care.
and an economic evaluation of the programme. This paper describes the study protocol of the evaluation of the RSE programme at patient level (figure 1, white boxes).

**Study cohort and participating centres**

Participant recruitment began in April 2013 and will continue until October 2015. The ReSpAct study enrolls participants with varying physical disability and/or chronic disease who participate in the RSE programme in one of the rehabilitation centres or hospitals involved. Like the general population, the group of participants will be heterogeneous, for example, for age, sex, PA behaviour, as well as for type and extent of disability. Box 1 shows details of eligibility criteria.

**Sample size**

PA is the main outcome measure and is assessed using an adapted version of the Short QUestionnaire to ASsess Health enhancing physical activity (SQUASH).38 Based on the numbers of patients enrolled in the study of van der Ploeg36 it was expected that subgroups of patients of n=500 were deemed necessary and feasible. The ReSpAct study aims to distinguish subgroups of patients based on two patient characteristics. Based on the context of rehabilitation, a first distinction is made between patients who received rehabilitation care in a rehabilitation centre (12 rehabilitation centres; n=1000) versus patients enrolled from the hospital (6 hospitals; n=500). In addition, subgroups of patients will be formed of inpatients (12 rehabilitation centres; n=200), outpatients (12 rehabilitation centres and 6 hospitals; n=1000) and patients who received treatment based on medicine consultation (6 hospitals; n=300). The target sample size in the ReSpAct study is 1500 patients. To achieve this number, a 25% attrition rate is factored in the recruitment plans. Therefore the study aims to recruit 2000 patients.

**The programme ‘RSE’**

**Content of the programme**

The PA and sport stimulation programme ‘RSE’ (Dutch: ‘Revalidatie, Sport en Bewegen’) is a programme aiming to stimulate an active lifestyle in persons with a physical disability and/or chronic disease subsequent to the rehabilitation period.39 The stages of change concept of the Transtheoretical model40 and the Physical Activity for people with a Disability (PAD) model41 formed the theoretical basis for the RSE programme. These models provide insight into the process of behavioural change and the relationships between PA behaviour, its determinants and the daily functioning of persons with a disability.

The RSE programme basically aims to stimulate an active lifestyle during the rehabilitation period and to guide patients in maintaining PA behaviour in the home setting (figure 2). At the start of the rehabilitation treatment, patients’ interests and wishes are identified and individual treatment goals are formulated with respect to participation in exercise and sports activities during rehabilitation. Then, by making sports and exercise an integrated part of the individual multidisciplinary treatment (eg, by physiotherapy, adapted PAs and occupational therapy), the patient has the opportunity to become acquainted with various PAs and to get more insight in their own abilities, interests and wishes regarding PAs and sports.

Three to 6 weeks before discharge, the patient is referred to a ‘Sports Counselling Centre’ (SCC) within a rehabilitation centre or a rehabilitation department of a general hospital. The SCC offers tailored counselling in
the form of individual consultations between the patient and a PA and sports counsellor. Counsellors working at the SCC are health professionals specialised in physiotherapy or adapted PA. The consultations at the SCC are intended to guide persons in their behavioural change with the aim to become/be physically active in the home setting after rehabilitation. During patient contact, the trained counsellors make use of MI, which is a client-centred style of conversation. MI has proven to be effective and seems well suited for use in a variety of healthcare settings.

After being referred to the SCC, the patient receives a 30 min individual face-to-face conversation (see figure 2). Dependent on the current patient's stage of behavioural change and patient' motivation for exercise and sports, the topics discussed are tailored to the patient needs. Any personal and environmental barriers and facilitators that may affect the process of behavioural change are also discussed. In addition, the patient receives a booklet on the stages of behavioural change related to an active lifestyle.

Following the first consultation and after discharge from rehabilitation, the patient receives four 10–15-min tailored telephone counselling calls over 13 weeks (see figure 2). With these calls, the patient is further supported in maintaining an active lifestyle. Attention is paid to the current PA status and stage of behavioural change. Furthermore, satisfaction with current activities, possible barriers and solutions to barriers are discussed. Offering the telephone counselling calls when the patient is at home again, is in line with the ecological models of PA that suggest that behavioural settings and the broader social context also influence uptake and maintenance of PA behaviour. Therefore, the home may provide a conducive environment to longer term adherence to PA. Besides, the patients have to restart and reorganise their lives after discharge, and have to get used to the new situation of having a disability. The counsellor might offer some help in this process of PA behavioural change.

In contrast to the programme of van der Ploeg, the RSE programme is also appropriate to be implemented in hospitals rather than only within rehabilitation centres. As a result of this, the RSE programme will better suit the complete target group of the rehabilitation care, namely inpatients, outpatients and persons who are treated based on medicine consultations by a rehabilitation physician in the hospital setting. For the latter group of patients, the programme usually consists only of the counselling part, since these patients do not undergo a multidisciplinary rehabilitation treatment.

Counsellors’ training in MI
Within each participating rehabilitation centre and hospital, 1–4 counsellors work at the SCC. All counsellors are referred to follow training in MI by a professional MI trainer, who is a member of the Motivational Interviewing Network of Trainers (MINT). The training consists of a 3-day training course, followed by one refresher-day and biennial refresh-mornings. The 3-day training course provides a comprehensive overview of the foundations of MI, the evidence base concerning behavioural change and the core counselling skills of the approach. The refresher-days aim to involve more deeply in MI. These MI training courses are organised by the Dutch organisation ‘Stichting Onbeperkt Sportief’ and are offered to all counsellors.

Recruitment
Patients who have been referred to the SCC and who meet the inclusion criteria regarding age receive written information about the study. During the first consultation at the SCC, the counsellor gives oral information if desired and checks the inclusion and exclusion criteria. Patients who are eligible and willing to participate are asked to sign an informed consent form.

Data collection and outcome measures
Participants are followed over time through standardised measurements at given regular measurement occasions in time (figure 2). Each measurement consists of filling out a set of questionnaires. The questionnaires can be completed on paper or digitally.

Timeframe of four measurements
The baseline measurement consists of three parts (table 1). In preparation for the first consultation at the SCC, patients fill out a short questionnaire on their daily habits. The refresher-day and biennial refresh-mornings are aimed to involve more deeply in MI. These MI training courses are organised by the Dutch organisation ‘Stichting Onbeperkt Sportief’ and are offered to all counsellors. Patients who are eligible and willing to participate are asked to sign an informed consent form. Participants are followed over time through standardised measurements at given regular measurement occasions in time (figure 2). Each measurement consists of filling out a set of questionnaires. The questionnaires can be completed on paper or digitally.

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Before the face-to-face conversation starts, patients are asked to fill out another short questionnaire on several psychosocial factors and patient’s motivation towards PA behaviour (part B). The last baseline questionnaire is filled out by the patient at home, after the first consultation (part C).

During the following measurements, the questionnaires are completed as one set (table 1). The second

Table 1: Complete overview on assessments and moments of assessment among participating patients in the ReSpAct study

<table>
<thead>
<tr>
<th>Domain</th>
<th>Variables/instruments</th>
<th>T0* (A)</th>
<th>T0* (B)</th>
<th>T0* (C)</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary and secondary outcomes</td>
<td>Adapted SQUASH, based on refs 38 53</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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</tr>
<tr>
<td></td>
<td>Sport activities as part of rehabilitation care and self-initiated sport activities</td>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Sedentary behaviour</td>
<td>Transport by motor vehicle, sitting, lying and sleeping</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Health-related quality of life</td>
<td>Adapted RAND-36, based on refs 54–67</td>
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<td>X</td>
<td>X</td>
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<tr>
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<td>Visual analogue scale on patient’s self-rated health</td>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Potential factors that help explain</td>
<td>Self-image related to sports (past)</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>differences in patients’ PA behaviour—patient characteristics</td>
<td>Self-image related to sports (current)</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>General</td>
<td>Demographics and anthropological data</td>
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<td></td>
<td>Weight and family and living situation</td>
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<td>X</td>
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<tr>
<td>Lifestyle</td>
<td>Alcohol use</td>
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<tr>
<td></td>
<td>Smoking</td>
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<td></td>
<td></td>
<td>X</td>
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<tr>
<td></td>
<td>Unexpected serious events</td>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Stage of change</td>
<td>Stage of change (past), based on ref 54</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Stage of change (current)</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
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<tr>
<td>Psychosocial factors</td>
<td>Perceived social support, based on refs 57 58</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Perceived barriers of being physically active, based on refs 59 60</td>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Perceived reasons to be physically active</td>
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<td>X</td>
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<tr>
<td>Motivation</td>
<td>Behavior Exercise Regulation Questionnaire61</td>
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<td></td>
<td>X</td>
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<tr>
<td>Medical status and medical history</td>
<td>Diagnosis</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
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<tr>
<td></td>
<td>Change of medical status</td>
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<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Acceptance of the disease/disability68 69</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td></td>
<td>Physical problems70</td>
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<td></td>
<td></td>
<td>X</td>
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<tr>
<td>Fatigue and pacing</td>
<td>Fatigue Severity Scale62 63</td>
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<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Perceived fatigue</td>
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<td></td>
<td></td>
<td>X</td>
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<td>X</td>
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<td>Average activity level</td>
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<td></td>
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<td>X</td>
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<tr>
<td></td>
<td>Pacing</td>
<td>X</td>
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<tr>
<td>Potential factors that help explain</td>
<td>Involvement counsellor in rehabilitation period</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>differences in patients’ PA behaviour—programme characteristics</td>
<td>Patient experience with the face-to-face consultation</td>
<td>X</td>
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<td>X</td>
<td>X</td>
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<tr>
<td>Treatment</td>
<td>Consultation Date, duration and methods of each contact</td>
<td>Assessed by C</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>MI applied for each patient contact</td>
<td>Assessed by C</td>
<td></td>
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<tr>
<td></td>
<td>MI applied for each patient contact</td>
<td>Assessed by C</td>
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<td></td>
<td>Patient–counsellor interpersonal interaction</td>
<td>Assessed by C</td>
<td></td>
<td></td>
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</table>

*Baseline measurement consists of three parts: A, B and C.
†C, counsellor.
MI, Motivational Interviewing; PA, physical activity; ReSpAct, Rehabilitation, Sports and Active lifestyle; SQUASH, Short QUestionnaire to ASsess Health enhancing physical activity.
measurement (T1) takes place 14 weeks after discharge from rehabilitation to get insight in the direct results of the RSE programme. Patients who receive treatment based on medicine consultation are approached 14 weeks after the first consultation. Follow-up measurements (T2 and T3) are assessed 33 weeks and 1 year after discharge (or after the first consultation).

Content of four measurements
Each measurement includes a set of validated questionnaires as well as new developed instruments that will be evaluated during data collection. The outcome variables are thoughtfully selected on theoretical and empirical consideration in order to come to a full set of parameters to reach the prescribed aims, while also trying not to challenge participants with too time consuming questionnaires. To check the possibility of completing a measurement within 1 h, and to determine whether all questions were clearly stated, a pilot test was conducted before data collection began. Several persons with a physical disability or chronic disease filled out the baseline questionnaires (ie, part A, n=6; part B, n=5; part C, n=5).

The outcome variables included in the ReSpAct study are summarised in table 1 and are explained in more detail below. In addition, questions about work and medical care consumption are included in order to answer additional research questions (figure 1). Finally, some questions about patients’ satisfaction and opinion about the RSE programme are included in the questionnaire as part of the process evaluation of the implementation of the RSE programme.37

Primary and secondary outcomes
Primary outcome: daily PA
Self-reported level of daily PA is the primary outcome of the ReSpAct study and is assessed with an adapted version of the SQUASH.38,39 The SQUASH is a self-reported recall questionnaire to assess daily PA of healthy adults based on an average week in the past month. In order to make the questionnaire applicable for wheelchair user patients, these patients are instructed to only count those activities when they are sitting in the wheelchair, rather than actively propelling. HR-QoL is assessed by an adapted version of the RAND-36.64,65,67 The RAND-36 is a self-reported questionnaire that assesses eight health concepts from which the physical and mental health summary scores can be derived. Higher scores represent better HR-QoL.64,65 In addition, a horizontal visual analogue scale was added to record patient’s self-rated health. The end points are labelled with ‘worst imaginable health status’ and ‘best imaginable health status’.

Explanatory factors
To be able to better explain the differences in patients’ PA behaviour after completion of the RSE programme, factors that are possibly associated with patients’ PA behaviour are examined. Those factors are explained in more detail below on the basis of a subdivision in: patient’s characteristics and characteristics of the RSE programme. The selection of the patient’s characteristics is based on the PAD model.41

Patient’s characteristics
Stages of change
Provided that the content of the programme is well tailored to the actual stage of behavioural change of the patient, it is expected that the patient’s stage of change is a possible predictor of patient’s PA behaviour after completion of the programme. To gain more insight into the PA behaviour change, patients are asked to fill out a ‘stages of change’ questionnaire. Participants have to choose one of five statements, corresponding to the different stages of behavioural change, according to the Transtheoretical model of Prochaska and DiClemente.40 At baseline, this question is answered about both the period before the rehabilitation process was started, and about the current situation. To determine whether the counsellor is able to assess the patient’s current stage of change well, the counsellor is asked to register the patient’s stage of change too, directly following each consultation.

Psychosocial variables
Several psychosocial variables are measured over time as possible explanatory variables of PA behaviour. First, the

At baseline, the patients are asked to indicate which PAs they perform in the context of the rehabilitation treatment and on their own initiative.

Secondary outcomes
Secondary outcomes include daily sedentary behaviour and health-related quality of life (HR-QoL). Sedentary behaviour, such as sitting and lying down, is assessed by a self-reported recall questionnaire which is developed by the authors of the SQUASH.53 As is carried out in the SQUASH, the activities are assessed based on an average week in the past month. In order to make the questionnaire applicable for wheelchair user patients, these patients are instructed to only count those activities when they are sitting in the wheelchair, rather than actively propelling. HR-QoL is assessed by an adapted version of the RAND-36.64,65,67 The RAND-36 is a self-reported questionnaire that assesses eight health concepts from which the physical and mental health summary scores can be derived. Higher scores represent better HR-QoL.64,65 In addition, a horizontal visual analogue scale was added to record patient’s self-rated health. The end points are labelled with ‘worst imaginable health status’ and ‘best imaginable health status’.

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Patient’s characteristics
Stages of change
Provided that the content of the programme is well tailored to the actual stage of behavioural change of the patient, it is expected that the patient’s stage of change is a possible predictor of patient’s PA behaviour after completion of the programme. To gain more insight into the PA behaviour change, patients are asked to fill out a ‘stages of change’ questionnaire. Participants have to choose one of five statements, corresponding to the different stages of behavioural change, according to the Transtheoretical model of Prochaska and DiClemente.40 At baseline, this question is answered about both the period before the rehabilitation process was started, and about the current situation. To determine whether the counsellor is able to assess the patient’s current stage of change well, the counsellor is asked to register the patient’s stage of change too, directly following each consultation.

Psychosocial variables
Several psychosocial variables are measured over time as possible explanatory variables of PA behaviour. First, the
Fatigue and activity pacing

Fatigue is a common symptom associated with a wide range of chronic diseases, and one of the strongest predictors of functional disability. In addition, fatigue is seen as a barrier to PA behaviour. The Fatigue Severity Scale (FSS) is used to assess fatigue. Predictors of functional disability. In addition, additional items. To assess perceived social support from family, friends and colleagues concerning PA, seven important items with strong factor loadings were selected from the questionnaire of Sallis et al, partly based on a previous selection of Papandonatos et al.

The Behavioral Regulation in Exercise Questionnaire (BREQ-2) is used to measure the continuum of behavioural regulation in exercise contexts, based on the self-determination theory of Deci and Ryan. Patients have to respond to 19 items on a five-point Likert scale. The questionnaire showed strong factorial validity in adults who participate in an exercise referral scheme.

In addition, 10 important barriers to and reasons for PA are assessed. The barriers were largely selected from the questionnaire used by van der Ploeg et al. For intention, self-efficacy, attitude, perceived social support and reasons to be physically active a higher score means a more positive value for this variable with respect to a physically active lifestyle. For the barriers to PA a higher score means that the patient experiences the barrier more often.

Characteristics of the RSE programme

The individual exposure to the RSE programme is dependent on the patient’s rehabilitation treatment and the characteristics of the guidance from the SCC. Rehabilitation treatment characteristics (ie, treatment form, duration of the treatment and context of rehabilitation) are registered by the counsellor. Characteristics of the counsellors’ guidance includes the methods of contact and the frequency and duration of contact. For each contact, the counsellor registers those aspects of programme dose.

As most counsellors are health professionals specialised in physiotherapy or adapted PA, they often work as a therapist next to their work at the SCC. The possible involvement of the counsellor as a therapist at the rehabilitation treatment of the patient is assessed.

Planned statistical analyses

Descriptive characteristics from the participants and the RSE programme will be explored and the univariate correlation structure for the continuous variables will be described. Multilevel analyses comparing subgroups of patients will be conducted on PA behaviour measurements. Multilevel analysis will be used to analyse repeated measures data because patient data can be
clustered within the context of rehabilitation (rehabilitation centre vs hospital) and the type of treatment (inpatient vs outpatient rehabilitation care). Furthermore, this technique allows for missing values and can correct for differences at the level of context of rehabilitation and type of treatment, the so-called group effects. If there are any differences at baseline between subgroups of patients, a correction in the analyses will be used for the value of the particular outcome variable at T=0. In addition, possible confounding and interaction effects will be identified and corrected for in the analysis. For all multilevel analyses, the MLwiN (Institute of Education, London, UK) statistical computer programme will be used. Level of significance will be set at p<0.05.

DISSEMINATION

Throughout the ReSpAct study, newsletters will be produced and forwarded to participants and health professionals working at the involved rehabilitation centres and hospitals in order to promote the study and provide updates on its progress. In addition, there is a website launched (http://www.respact.nl) to inform all interested parties about the ReSpAct study.

The results of the ReSpAct study will be disseminated to the scientific, medical and general public. Results will be published in peer-reviewed international journals and will be presented at national and international conferences and symposiums. In addition, results and their practical implications will be disseminated by meetings with clinicians and those interested in rehabilitation care and the stimulation of an active lifestyle among patients with a physical disability or chronic disease.

Author affiliations

1Center for Human Movement Sciences, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands
2Department of Rehabilitation Medicine, Center for Rehabilitation, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands
3Research and Innovation Group in Health Care and Nursing, Hanze University of Applied Sciences, Groningen, The Netherlands
4Centre of Sport and Exercise Science, School of Biological Sciences, University of Essex, Colchester, UK
5Center for Sports Medicine, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands

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Protocol of a longitudinal cohort study on physical activity behaviour in physically disabled patients participating in a rehabilitation counselling programme: ReSpAct

Rolinde A Alingh, Femke Hoekstra, Cees P van der Schans, Florentina J Hettinga, Rienk Dekker and Lucas H V van der Woude


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