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Protocol and pilot study of a short message service-guided training after acute stroke/transient ischemic attack to increase walking capacity and physical activity☆,☆☆

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ABSTRACT

Physical activity in community-living individuals after a stroke is usually scarce. This protocol describes a study that will evaluate a method to increase physical activity by performing a 3-month outdoor walking and muscle strengthening program and will examine the 3-month and 1-year effects of this program on individuals with acute stroke (AS) or transient ischemic attack (TIA). In a prospective randomized controlled trial in Uppsala, Sweden, 80 individuals with AS or TIA who maintained cognitive and motor function will be randomized into groups for continuous training for three months or for regular standard care. The training will be supervised by daily cellphone-delivered messages (short message services; SMS), and the intensity, duration and workload will be gradually increased. The primary outcome is a change in walking capacity according to the 6-Minute Walk Test and chair-rising at three months. Secondary outcomes include mobility, gait speed, handgrip strength, body composition (fat mass and muscle mass), biochemical risk-markers, health-related quality of life, and cardiovascular events. Adherence to the training program will be documented with a self-reported diary and step counts over two weeks. The major study started in November 2016, and results are expected in 2019. In a pilot study of 15 subjects post-stroke (mean-age 65 years), we observed improved walking capacity (increasing from 23 to 255 m) and chair-rising (decreasing 2.42 s) from baseline to three months. SMS-guided outdoor training will be tested as a potential therapeutic strategy to increase physical activity and thereby improve walking capacity and physical function following a stroke.

1. Introduction

Acute stroke (AS) and transient ischemic attack (TIA) are diagnosed in approximately 26,500 and 8000–12,000 persons/year, respectively, in Sweden according to the Swedish Stroke Register (RIKSstroke, 2017). In the United States, approximately one person every 40 s experiences a stroke, and the prevalence is projected to increase by 25% until 2030 (Mozaffarian et al., 2016). Worldwide, older adults, black people and people with lower levels of education have a higher stroke prevalence (Mozaffarian et al., 2016). Approximately 75% of stroke victims are 70 years or older at stroke onset (RIKSstroke, 2017). However, in Sweden, the incidence of stroke is increasing in people aged 35–44 years despite a decrease in the overall incidence of stroke (RIKSstroke, 2017). Approximately two-thirds of the strokes occurring in Sweden are considered to be mild (RIKSstroke, 2017). An example of improved secondary prevention consists of smoking cessation and medical treatment with oral anti-coagulants, anti-hypertensive treatment and cholesterol-lowering treatment (Billinger et al., 2014). However, secondary prevention programs aiming at increased physical activity are scarce. Worldwide, physical inactivity is known to be the fourth leading risk factor for mortality, and > 80% of adolescents worldwide are insufficiently physically active (WHO, 2016). Inactivity (i.e., no sessions of light/moderate or vigorous physical activity of 10 min or more) gradually increases with age from 24.8% (ages 18–44 years) to 51% (≥75 years of age) (Mozaffarian et al., 2016). Thus, hospital- and community-based studies consistently show even lower levels of physical activity among stroke survivors (Mozaffarian et al., 2016; Billinger et al., 2014); for example, one observational study

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indicated that people spent close to 11 h sitting per day following a stroke (English et al., 2016). Community-living individuals who suffer from a stroke have a 23% lower level of physical activity compared to individuals of the same age who have not suffered a stroke, as measured by the Physical Activity Scale for the elderly (Danielsson et al., 2014). In people suffering from a stroke, physical activity lowers the risk of stroke, coronary heart disease and premature mortality by improving risk-factors related to metabolic syndrome, i.e., hypertension, diabetes, hyperlipidemia and accumulation of body fat (Mozaffarian et al., 2016; Esenwa and Gutierrez, 2015). Outdoor walking with gradually increased intensity and strength training might be one way to achieve increased physical activity (Billinger et al., 2014).

In the guidelines for individuals with stroke, training should include low- to moderate-intensity aerobic activity and muscle-strengthening exercises (in bouts of 10 min or more); a reduction in sedentarism; and secondary risk management (Billinger et al., 2014). Studies evaluating walking capacity or aerobic training after stroke are usually performed in the subacute or chronic stage using a cycle ergometer or walking on a treadmill (Saunders et al., 2013). Outdoor walking and home-based strength training are cost-effective and easy to perform in most surroundings. Currently, more research is needed to establish the effect of outdoor walking interventions on physical function and health, in both the acute and more chronic stages after a stroke (Saunders et al., 2016).

The general trend is that hospital stays become shorter. Thus, it is important to find cost-effective and user-friendly methods for training after an acute stroke. The use of cellphones is a common way to communicate today and might improve the motivation to exercise. Cellphone-based rehabilitation, such as delivering an SMS for secondary prevention of cardiovascular diseases, seems to be effective (Gandhi et al., 2017; Varnfield et al., 2014). To date, no studies have been conducted to determine whether an outdoor community walking and muscle strength training program delivered via SMS following AS/TIA can improve physical functioning and metabolic profiles (Billinger et al., 2014; English et al., 2016; English et al., 2014).

1.1. Purpose and aims

The Strokewalk study was designed to evaluate if a method consisting of daily cellphone-delivered messages with training instructions for three months is better than the current standard of treatment to improve physical activity, physical functioning and biomarkers related to cardiovascular disease in people discharged from the hospital with AS or TIA for up to one year.

The primary outcome and hypothesis is that SMS-delivered training instructions will increase walking capacity compared with the current standard of treatment. Secondary outcomes and hypotheses are that the program will increase physical functioning (i.e., mobility, gait speed and hand-grip strength), improve body composition (lower fat mass and increased muscle mass), improve biochemical cardio-metabolic risk markers, decrease further cardiovascular incidents and improve the health-related quality of life (HRQoL)/self-perceived health.

2. Materials and methods

2.1. Study participants

Eligible participants are adults with verified AS or TIA, aged 18 years or older, scheduled to be discharged to an independent living situation and with a sufficient walking capacity, which is the ability to perform the 6-minute walking test (6 MWT) (Am. J. Respir. Crit. Care Med., 2002). Cognitive function, measured with the Montreal Cognitive Assessment scale (MoCA), must be ≥ 23 points (Nasreddine et al., 2005). Motor function, according to the Modified Rankin Scale (MRS), has to show a slight disability or less with a score of ≤ 2 (Banks and Marotta, 2007). Individuals with a MRS score of 3 with moderate disability are excluded since they requires some help and are more likely in need of hospital-based rehabilitation. The participants need to have access to a cellphone.

Exclusion criteria are subarachnoid hemorrhage, medical problems such as uncontrolled hypertension, untreated arrhythmias, significant valvular or coronary disease, unstable cardiovascular status, dementia, severe aphasia or cognitive impairment with difficulty understanding instructions.

2.2. Study design

This is a prospective, randomized, controlled two-armed trial, conducted in the stroke-unit at the Uppsala University Hospital, Sweden. Ethical approval for the present study, which complies with the Helsinki Declaration, was obtained from the Regional Ethical Review Board of Uppsala University Hospital; Dnr: 2015/550.

Ethical approval for the pilot study, which complies with the Helsinki Declaration, was obtained from the Regional Ethical Review Board of Uppsala University Hospital; Dnr: 2015/358. Data for the pilot study were collected from October 2015 to May 2016.

2.3. Informed consent

Written and verbal information about the study are provided simultaneously during the hospital stay, and all participants have to give their signed informed consent before screening for eligibility and enrollment. A flow-chart of the study design is shown in Fig. 1.

2.4. Data collection – study protocol

Patients are screened for sufficient walking capacity, cognition and motor function before entering the study. All patients will be examined at baseline, after three months with intervention and one year after stroke/TIA. Cognition, motor function, nutritional status, stress and physical activity are measured as baseline characteristics. Changes in walking capacity, physical functioning (mobility, gait speed and hand-grip strength), body composition and blood levels of cardio-metabolic risk markers will be analyzed after three months of intervention. The assessments, except for those of body composition, will be performed by one of the authors (BV) before randomization, at the start of the intervention and at the end of the intervention at 3 months. BV will be blinded to the group allocations throughout the study. At one year, between group differences in register-based data on all-cause mortality, cardio-vascular incidences and health-related quality of life will be collected from the Swedish stroke register (RIKSstroke, 2017). A flow-chart of measurements at baseline, three months and one year is provided in Fig. 1.

Walking capacity and lower extremity performance are the primary outcomes of the present study. The 6 MWT (Am. J. Respir. Crit. Care Med., 2002) used in this study evaluates walking capacity. The maximal distance at a maximal pace over a 30 m course during 6 min is recorded (Am. J. Respir. Crit. Care Med., 2002). Heart rate is measured by an oximeter (Collinor®), and the perceived rate of exertion is rated on the Borg's rating of perceived exertion (RPE) scale® (Borg, 1982), ranging from 6 (nothing at all) to 20 (maximal).

The sit-to-stand test, one item of the SPPB, evaluates functional lower extremity strength, with the individual rising up from a seated position as quickly as possible 5 times (Guralnik et al., 1994; Mong et al., 2010).

The Montreal Cognitive Assessment scale (MoCA) (Nasreddine et al., 2005) (0–30 points) will be used to assess cognition. A sum score of < 26 is often used as cut-off point for no cognitive problems (Nasreddine et al., 2005).

The Modified Rankin Scale (MRS) (Banks and Marotta, 2007) will be used to assess motor function. It is a measure of global disability. It is scored from 0 (no symptoms at all) to 6 (dead) with 3 indicating moderate disability: requiring some help but able to walk without

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