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Study protocol: Adjusting the challenge-skill balance for occupational therapy in a recovery rehabilitation unit: A proposal for a randomized controlled trial

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Study protocol: Adjusting the challenge-skill balance for occupational therapy in a recovery rehabilitation unit: A proposal for a randomized controlled trial

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Abstract

Introduction: Occupational therapy is defined as the promotion of client health and wellbeing through client-centered practice. However, there is a tendency to rely on the therapist's experience and values, and there is a difference between the client's and therapist's perceptions of the activity engaged in by the client. In previous studies that have applied "flow," activities supported by the occupational therapy of elderly people were analyzed, indicating that there is a difference in recognition. Therefore, we thought that more effective occupational therapy could be implemented by adjusting the challenge-skill balance, and invented a process called adjusting the challenge-skill balance for occupational therapy (ACS-OT). The purpose of this study was to verify the effect of ACS-OT with clients in the recovery rehabilitation unit, and to prepare a protocol for randomized control trial (RCT) implementation.

Method and Analysis: This single-blind RCT will recruit eighty 50–99-year-old clients admitted to the recovery rehabilitation unit who meet certain eligibility criteria. Clients will be randomly allocated to receive either occupational therapy with an adjusted challenge-skill balance process or standard occupational therapy. Both interventions will be carried out during clients' residence at the unit. Outcomes will be measured at entry to ("pre") and discharge from ("post") the unit, and then three months afterwards ("follow-up"). The primary outcome measure will be subjective quality of life.

Ethics and Dissemination: This protocol has been approved by the Ethics Review Committee of the Tokyo Metropolitan University (No.17020). Results of this trial will be submitted for publication in a peer-reviewed journal.

Trial registration: University Hospital Medical Information Network 2017 UMIN000029505.

Strengths and limitations of this study

- This is the first prospective randomized controlled trial to verify the effect of Adjusting the challenge-skill balance for occupational therapy (ACS-OT) in the recovery rehabilitation unit.
- Verify whether the new occupational therapy process called ACS-OT is effective for subjective quality of life.
- The sample size is set appropriately by power analysis based on our previous research results.
- Stratified randomization is responsible for homogeneous assignment of experimental groups and control groups.
- It is impossible to blind implementers due to the nature of the intervention in occupational therapy process.
- Acute patients, subacute patients, outpatients, and clients who use community rehabilitation services are not included.

Background

Rehabilitation aims to maximally promote the process of recovery from injury, illness, or disease, supporting the client to reach a normal condition. An occupational therapist is a health professional who aims to support the achievement of independence, meaning, and satisfaction in all aspects of people's lives. Likewise, occupational therapy is defined as a profession that promotes clients' health and wellbeing through client-centered practice. In many countries, client-centered practices are the basis for occupational therapy [1-5]. In saying this, within processes related to client-centered practice, there is a tendency to rely on the therapist's experience and values. It has been reported that there is a difference between the client's and therapist's perceptions of the activity engaged in by the client [6-7]. To support the activity desired by the client, we believe that it is necessary to obtain the client's evaluation of the activity, in a form that the client and the therapist can easily share. In addition, deterioration of the client's health condition, physical and mental functions, and loss of social role often causes decreased motivation to perform the activities [8-9]. Therefore, in occupational therapy, we consider that it is necessary for clients and therapists to easily share the meaning of activity, and to provide support that facilitates positive client mental state. To reflect this in our research, we decided to apply "flow," a concept that captures the psychological state of activity. Flow is defined as "the state in which people are so involved in an activity that nothing else seems to matter at the time; the experience is so enjoyable that people will do it even at great cost, for the sheer sake of doing it" [10]. With regard to research on flow in relation to the occupational therapy field, there have been reports of improved happiness, self-esteem, work productivity, and level of subjective wellbeing [11-16]. According to Csikszentmihalyi [10], flow can be explained according to the balance between challenge and skills; the "flow model." Flow is experienced when an individual's perception of the difficulty associated with an activity is balanced with their level of skill. In contrast, activities in which the individual's skill is perceived to be close to the difficulty associated with the activity leads to boredom. Similarly, conditions of low-perceived skill and high-perceived challenge produce anxiety, while conditions of low-perceived skill and low-perceived challenge result in apathy. Several research reports have analyzed the relationship between the flow model and health-related quality of life (QOL) [17-21]. In our research using the flow model, we analyzed activities supported by occupational therapy for the elderly using an adult day program, and showed that there was a difference in recognition [7]. In other words, even within conventional client-centered occupational therapy, there is a difference in recognition from the viewpoint of challenge and ability. Therefore, we believed that more effective occupational therapy could be provided by adjusting these, and invented a new process called adjusting the challenge-skill balance for occupational therapy (ACS-OT). A previous randomized controlled trial (RCT) on ACS-OT for the elderly using an adult day program showed improvements in health-related QOL [22]. To generalize the results of this research to various fields, it is necessary to develop research in this area. The purpose of this study is to verify the effect of ACS-OT in the recovery rehabilitation unit of Harue Hospital, Fukui, Japan, and to determine a protocol for RCT implementation.

Method/design

Design

This study has been designed as an RCT comparing occupational therapy with an adjusted challenge-skill balance process to standard occupational therapy. Clients 50–99 years old admitted to the recovery rehabilitation unit will be eligible for this study.

The primary outcome measure will be change in subjective QOL, which will be compared between the experimental and control groups. The secondary outcome measure will be change in flow experience, health-related QOL, and performance of activities of daily living.

Feasibility of recruitment and sample size

Based on the results of a previous RCT in the field of occupational therapy, whose QOL effect size was 0.76 [22], we have conducted an a priori power analysis (using G*power, version 3.1.7) [23] that assumed a medium-to-large effect size. The analysis indicated that a total sample size of 68 clients (34 in each of the two groups) would provide 80% power for detecting a difference, with an effect size of 0.7 in health-related QOL scores using a two-tailed test and an alpha level of 0.05. To compensate for possible loss, we have decided to enroll 80 clients. We aim to reach this in approximately one year.

Randomization

As aforementioned, this study has been designed as a single-blind RCT that will be reported in accordance with the CONSORT guidelines [24] for reporting clinical trials. Clients will be randomly assigned by blocked randomization (block size four) to either the experimental or the control group. As the factors within the experimental and control groups affecting the outcome measures are homogeneous, randomization will be stratified by disease group (cerebrovascular disease/musculoskeletal disease) and a visual analog scale for the self-assessment of general health in EuroQol-5 Dimensions (EQ-5D) [EQ-VAS (high/low, boundary 50)] [25] will be performed, resulting in four layers: 1. cerebrovascular disease & high EQ-VAS; 2. cerebrovascular disease & low EQ-VAS; 3. musculoskeletal disease & high EQ-VAS; and 4. musculoskeletal disease & low EQ-VAS. Block order will be randomly assigned using computer-generated software (R. Ver. 3.2.1). The statistician will create a block random pattern for each layer, and will notify the occupational therapists of the assignment result. The clients will be blinded to group allocation, although the therapists will be aware of the treatment assigned. After the last outcome measurement point, each client will be asked if they know their assigned group.

Inclusion and exclusion criteria

Inclusion criteria for this study will be clients with cerebrovascular or musculoskeletal disease admitted to the recovery rehabilitation unit of Harue Hospital, Fukui, Japan. Clients under the age of 50 years and older than 100 years at the time of their admission to the unit will be excluded from the study. In addition, clients whose Mini-Mental State Examination (MMSE) score is assessed as 23 points or less at their first occupational therapy appointment after admission to the unit will be excluded from the study [26].

Procedure

Intervention

In both the experimental and control groups, occupational therapy will be provided in accordance with the American Occupational Therapy Association guidelines [27]. The study intervention will be implemented by occupational therapists who are experienced (at least 200 work hours) in delivering treatment according to client-centered occupational therapy. Moreover, the therapists will be trained (at least 50 hours) on adjusting the challenge-skill balance process in occupational therapy. The occupational therapy program will focus on the occupational performance of activities and be conducted individually. The difference between the two groups will be whether the evaluation and intervention are conducted based on an appropriate challenge-skill balance. Treatment will consist of 40–60 minute sessions conducted six times per week. The implementation period will be from admission to the recovery rehabilitation unit to discharge.

Experimental group

1. During the first session of occupational therapy, the therapist will assess the client's problems in activities of daily living using the Canadian Occupational Performance Measure [28]. Based on the problems identified, activities that could be supported by occupational therapy will be selected.
2. During the second session, the client will perform the selected activities, and will then be invited to evaluate the activities using the challenge and skill levels. "Challenge level" will be defined as the client's perception of the level of difficulty associated with the activity, and will be rated on a seven-point scale from "very simple" (1) to "very difficult" (7). "Skill level" will be defined as the client's perception of their skills in relation to the activity, and will be rated on a seven-point scale from "not at all" (1) to "very skillful" (7) [29-30]. At that time, the therapist will clarify with the client the reasons for their challenge and skill level ratings.
3. Based on the client's and therapist's evaluations, the factors that make the client's occupational performance difficult ("challenge components," such as environment, execution time, and size of the location in which the activity occurs) and factors that improve their occupational performance ("skill components," such as frequency, range, distance, accuracy, and dexterity) will be determined.
4. Based on these components, adjustments to the challenge-skill balance of the activities will occur. The criteria for judging that the challenge skill balance has been adjusted is defined in terms of the difference between the "challenge level" and "skill level" of occupational therapist and client is 1 or less respectively .

5. After the client has performed the adjusted activities, the client's challenge-skill levels will then be re-evaluated. When the client's challenge-skill levels are balanced, interventions centered on the improvement of performance of the activities will commence. If the client's challenge-skill levels are not balanced, the activities will re-adjusted and the intervention will be started once the levels are balanced. The intervention will aim to improve the client's skill levels on the activities once their challenge-skill levels have been balanced.
6. This process will occur at least once a week.

Control group

For the control group, the first and second sessions will be conducted the same as for the experimental group, except that the therapists will not be informed of the client's subjective perception of the challenge and skill levels for the activities. From the third session onwards, the therapists will simply assess the client's performance and conduct the therapy in a manner typical of occupational therapy, following the general guidelines for occupational therapy practice.

Outcomes

As aforementioned, outcomes will measured at entry to ("pre") and discharge from ("post") the unit, and three months afterwards ("follow-up"). The primary outcome measure will be subjective QOL. All outcomes to be measured are listed below.

Subjective quality of life (pre, post, and follow-up)

Ikigai-9 is a self-assessed psychological measure of an individual's mental state (reason for living; ikigai) and QOL [31]. It consists of nine items, and a total score (nine–45 points) and three subscale scores (three–15 points each) are calculated.

Health-related quality of life (pre, post and follow-up)

Health-related QOL will be assessed using the EQ-5D. The EQ-5D defines health along five dimensions (mobility, self-care, day-to-day activities, pain and discomfort, and anxiety or depression). The EQ-5D also has a visual analog scale (the EQ-VAS) that enables self-assessment on a scale from zero (worst possible health) to 100 (best possible health).

Flow experience (pre and post)

Flow experience will be assessed using the Flow State Scale for Occupational Tasks [32], developed for clinical situations, which consists of 14 items and three factors (possible scores range from seven–98). The measure's reliability and validity have previously been confirmed [32].

Activities of daily life (pre and post)

Activities of daily life will be measured using the Functional Independence Measure (FIM) [33]. The FIM is an 18-item, seven-level scale that uniformly assesses the severity of an individual's disability and medical rehabilitation functional outcome (possible scores range from seven–126).

Clinical global impression (post)

The Clinical Global Impression (CGI) rating scales are measures of overall treatment improvement. The CGI is rated on a seven-point scale, with the severity of illness scale using a range of responses from one (very much improved) to seven (very much worse) [34]. The CGI is used to determine

Minimally Important Change (MIC) [35] in the main outcome.

Evaluation of implementation status for occupational therapy (post)

Evaluation of ACS implementation status will be carried out by the occupational therapists. This evaluation is rated on a seven-point scale and consists of the following three items: 1. Ability to identify the difference in recognition about the activity between the client and the therapist; 2) Whether the differences in recognition between the client and the therapist were adjusted during occupational therapy; 3) Whether occupational therapy suitable for the client was provided.

Organization

A primary investigator will be responsible for the informed consent procedure, measurements, analysis, and study report. The primary investigator will be assisted by three research assistants. Data entry and control will be conducted by the research assistants under the supervision of the investigator. A statistician will be responsible for the data analysis.

Statistical analysis

All statistical analyses will be performed using SPSS Ver. 24.0 for Macintosh. Data will be entered into Microsoft Excel 2016 and subsequently exported into SPSS software for analysis. The analysis will be undertaken by the statistician, who will be blinded to the random assignment result. Baseline characteristics of the groups will be compared using Chi-square and independent t-tests for the categorical variables, and the Mann–Whitney U test for continuous variables. Primary analysis for this study will be undertaken using intention to treat principles.

Generalized linear mixed model

Each continuous outcome variable will be analyzed using a generalized linear mixed model (GLMM) fitted with a maximum likelihood estimation. We will include the following as fixed effects: group allocation (experimental or control group), time (pre, post, or three-month follow-up), and the interaction of group and time. In addition, we will include the participants as a random effect. All confidence intervals will be provided with 95% margins.

Analysis of covariance

Treatment differences between the three timepoints (pre and post, pre and three-month follow-up, and post and three-month follow-up) will be evaluated using analysis of covariance (ANCOVA), with the pre-test scores on the Ikigai-9 and the EQ-5D as covariates. This analysis is regarded as a post hoc test after the implementation of the GLMM. The ANCOVA will also use an analysis of the FIM and EQVAS scores between the pre and post timepoints. For all tests, a two-sided significance level of < 0.05 will be used. We will also report significance according to Benjamini and Hochberg's method [36] regarding the adjustment of the overall score as a false discovery rate.

Between-groups effect sizes will be calculated as standardized mean differences (Cohen's d).

Minimal importance change

Minimal importance change (MIC) for each outcome will be calculated using the anchor-based method [37]. The area under the receiver operating characteristic curve will be able to identify the

cut‐off point on the CGI scores that most optimally distinguishes between CGI scores of minimal improvement (one–three) and scores of no difference (four–seven). The cut‐off will be used to provide an MIC estimate that will maximize the Youden J statistic: sensitivity‐ (one‐specificity) [38].

Cost-effectiveness

A cost-effectiveness analysis will be performed using total cost and quality-adjusted life years (QALYs) based on the index value of EQ-5D, and incremental cost-effectiveness ratios (ICERs) will be calculated based on comparisons of the experimental and control groups. Total cost will be converted to US dollars using the average currency exchange rate at the time of data analysis. The ICER will be estimated using the following equation: ICER = [μCe− μ Cc]/[μEe− μ Ec], where μC and μE represent the mean cost and mean QALY for the experimental and control groups, respectively. To account for the uncertainty of ICER, the bootstrap method (1000 times) will be used to calculate the mean values [39].

Ethics

This protocol has been approved by the Ethics Review Committee of the Tokyo Metropolitan University (No.17020).

Discussion

This research protocol has been prepared to examine the effect of adjusting the challenge-skill balance process in occupational therapy on subjective QOL of clients in a recovery rehabilitation unit, using an RCT. The main purpose of occupational therapy is to make it possible for clients to participate in the activities of daily life that they desire. To achieve this, practical models such as the Canadian Model of Occupational Performance [40] and Model of Human Occupation [41] are advocated. On the other hand, Maitra [6] conducted a questionnaire survey and reported that there was a difference in perception between the occupational therapist and the client, even though it seemed that the therapist had provided client-centered occupational therapy. Thus, it is necessary to facilitate the sharing of the meaning of “occupation” between the therapist and the client, in order to understand and support the client’s desired activities. The process used in this study was devised based on the flow model and shares perception of the activities between client and occupational therapist, as well as highlighting the importance of the provision of appropriate activities for clients. The client’s perception of their challenge-skill balance is highly relevant to the degree of difficulty and occupational performance of activities provided by occupational therapy.We believe that understanding the client’s subjective assessment of their activities, according to their challenge-skill balance, supports the provision of effective occupational therapy.

This study has been designed as an RCT. To verify the effect on this occupational therapy process, we believe that this research design is necessary to more clearly show the effect of the intervention. In addition, we aim to homogenize the two groups by stratified blocking using disease and

subjective health. We have not set strict age limits as inclusion criteria, as this process is assumed to be adaptable to clients of a wide range of ages.

A previous RCT that used a similar protocol for older adults in an adult day program resulted in improved health-related QOL [22]. However, in this study design, only one activity was focused and a follow-up period was not set. This protocol will cover several activities with which clients require assistance during admission to a recovery rehabilitation unit. Furthermore, by setting the follow-up period, we will verify the continuity of the effect in addition to the direct effect of ACS-OT implementation. We hypothesize that ACS-OT will enhance the effects of positive emotions and self-affirmation by facilitating activities suitable for clients, and as such subjective QOL according to the Ikigai-9 has been adopted as the main outcome. This suggests that occupational therapy may yield new findings on the effect on subjective QOL. In addition, by using a GLMM, it will be possible to perform an analysis that considers individual differences as a random effect.

Study limitations

In the effectiveness verification in the recovery rehabilitation unit, there is a high possibility that there will be a positive influence on the outcome as conditions improve in the control group, as well as in the experiment group [42-43]. Therefore, there may be no clear difference between the two groups. For example, the ADL score can probably be expected to improve in the two groups. Taking these into consideration, the main outcome measure of subjective QOL has been selected, which is expected to be most effective. While subjective evaluations such as subjective QOL, health-related QOL, and flow experience is highly likely to result in measurement bias. With regard to this point, we will devise measures to reduce this bias as much as possible, by adopting an RCT design and carrying out self-assessed outcome measurements.

Also, since the frequency of ACS implementation in the experiment group in this study is about once a week, thereon in, there may be cases where the effect of the intervention is not maintained throughout the support period. In addition, there are concerns that the adjustment process may not be able to function sufficiently if there are multiple activities to support, and when a client's activities are frequently changed according to their recovery stage. Furthermore, an occupational therapist who has experienced the adjustment process may inadvertently provide similar support to the control group as the experiment group. If that were to happen, the differences between the experimental and control groups may be inconspicuous.

We will use a convenience sample from the recovery rehabilitation unit of a single hospital, which may not be representative of all clients in a recovery rehabilitation unit. This study will not include acute patients, subacute patients, outpatients, and clients who use community rehabilitation services. Therefore, our results will not be able to be generalized to these populations. In view of these limitations, we will comply with the protocol and show the effect of adjusting the challenge-skill balance process.

Conclusions

In the occupational therapy process, it is important to share the perceptions between occupational therapists and clients, and provide appropriate assistance to the clients. Therefore, We believe that it is useful to verify the effect of adjusting the challenge-skill balance process for occupational therapy by conducting an RCT. This research will aim to contribute to the development of a more effective occupational therapy process that leads to improvements in clients' subjective QOL, in addition to improving their activities of daily living and health-related QOL.

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Footnotes

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D. REHABILITATION MEDICINE, Occupational therapy, Flow model, Randomized control trial

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Abstract

Introduction: Occupational therapy (OT) is defined as the promotion of client health and well-being through a client-centered practice. However, there is a tendency to rely on the therapist's experiences and values, and there is a difference between the client's and therapist's perceptions regarding the current activity that the client is engaged in. In previous studies that have applied "flow," activities supported by OT in elderly people were analyzed, indicating a difference in recognition. Therefore, we thought that more effective OT could be implemented by adjusting the challenge–skill balance, and we invented a novel process termed as adjusting the challenge–skill

balance for OT (ACS-OT). The purpose of this study is to verify the effect of ACS-OT on clients in the recovery rehabilitation unit and to prepare a protocol for randomized control trial (RCT) implementation.

Method and Analysis: This single-blind RCT will recruit 80 50–99-year-old clients admitted to the recovery rehabilitation unit who meet eligibility criteria. Clients will be randomly allocated to receive ACS-OT or standard OT. Both interventions will be performed during the clients' residence at the unit. The primary outcome measure will be subjective quality of life and will be measured at entry into (pre) and at discharge from (post) the unit and at 3 months afterwards (follow-up). Outcomes will be analyzed using a generalized linear mixed model fitted with a maximum likelihood estimation.

Ethics and Dissemination: This protocol has been approved by the ethics review committee of the Tokyo Metropolitan University (No.17020). Results of this trial will be submitted for publication in a peer-reviewed journal.

Registration: University Hospital Medical Information Network 2017 UMIN000029505. Registered on October 11, 2017.

Strengths and limitations of this study

- This is the first prospective randomized controlled trial (RCT) to verify the effect of a new occupational therapy (OT) process termed as adjusting the challenge–skill balance for OT (ACS-OT) in the recovery rehabilitation unit.
- We designed a RCT to verify if ACS-OT is effective in improving subjective quality of life.
- Stratified randomization is responsible for homogeneous assignment of experimental group and control group.
- Outcomes analysis using clients as random effect by linear mixed model.
- It is impossible to blind the therapists because of the nature of intervention in the OT process.
- Patients with acute and subacute conditions, outpatients, and clients who use community rehabilitation services will be excluded.

Background

Rehabilitation aims to maximally promote the process of recovery from injury, illness, or disease, supporting the client to reach a normal condition. An occupational therapist is a health professional who aims to support the client to return to independence, meaning, satisfaction in all aspects of people's lives. Likewise, occupational therapy (OT) is defined as a profession that promotes clients' health and well-being through a client-centered practice. In many countries, client-centered practice is the basis for OT; this practice contributes to the realization of meaningful activities for the client [1-5], which are defined as familiar activities which aligns with an individual's pursuit of valued developmental goals to maintain a personally meaningful lifestyle [6-7]. In saying this, within processes related to a client-centered practice, there is a tendency to rely on the therapist's experience and values. There is a difference between the client's and therapist's perceptions regarding the activity engaged in by the client [8-9]. To support the activity *desired* by the client, it is necessary to determine the client's evaluation of the activity in a form that the client and the therapist can easily share. In addition, deterioration of the client's health and physical and mental functions, and loss of social role often causes decreased motivation to perform these activities [10-11]. Therefore, in OT, it is necessary for clients and therapists to easily share the meaning of activity and to provide support that facilitates positive client mental state. To reflect this in our research, we applied the concept of "flow," which captures the psychological state of a particular activity. Flow is defined as "the state in which people are so involved in an activity that nothing else seems to matter at the time; the experience is so enjoyable that people will do it even at great cost, for the sheer sake of doing it" [12]. With regards to research on flow in the OT field, there have been reports on improved happiness, self-esteem, work productivity, and subjective well-being level [13-18]. According to Csikszentmihalyi [12], flow can be explained according to the balance between challenge and skills, i.e., the "flow model." Flow is experienced when an individual's perception of the difficulty associated with an activity is balanced with their level of skill. Conversely, activities in which the individual's skill is perceived to be too close to the difficulty

associated with the activity leads to boredom. Similarly, conditions of low-perceived skill in a high-perceived challenge result anxiety, whereas conditions of low-perceived skill and low-perceived challenge result in apathy. Several cross-sectional studies using the flow model have been reported [19-23]. In our previous research using the flow model to shape the OT practice, although the occupational therapist judged the activity to be suitable for the clients, clients themselves felt that the activity made them feel anxious, bored, and apathetic [9].

We believe that more effective OT and realization of meaningful activities for clients could be provided by adjusting the challenge–skill balance. Therefore, we invented a new process called adjusting the challenge–skill balance for OT (ACS-OT). A randomized controlled trial (RCT) conducted using ACS-OT for the elderly in an adult day program showed improvements in health-related quality of life (QOL) [24]. However, this previous research only tested one activity, which limits the generalization of the effect of ACS-OT on the larger population and to different activities. Therefore, we propose to examine the effect of ACS-OT on clients in the recovery phase who need timely support on activities of daily living (ADL) and occupational performance necessary to return to their home life. To test this, we plan to employ ACS-OT in the recovery rehabilitation unit of Harue Hospital, Fukui, Japan, and to determine a protocol for RCT implementation.

Method and Analysis

This study is designed as RCT for comparing ACS-OT with standard occupational therapy (control). To minimize heterogeneity of the client sample, we will test clients aged 50–99 years old admitted to the recovery rehabilitation unit. This age range was chosen as the average age of patients admitted is 76.8 ± 12.7 years, and we extended the target age range to ± 2 standard deviations. As discussed in a previous review [25], this study represents the practice of client-centered OT, focusing on ADL and occupational performance. To determine if ACS-OT could be effective with various diseases, we targeted cerebrovascular and musculoskeletal disease, which are the main

diseases observed at our recovery rehabilitation unit. The average admission period in this unit is 8–10 weeks for cerebrovascular disease and 6–8 weeks for musculoskeletal disease. The intervention period in this study is set to 6–10 weeks, and the number of interventions would be 36–60. The primary outcome measure will be change in subjective QOL, which will be compared between the experimental and control groups. The secondary outcome measure will be change in flow experience, health-related QOL, and performance of ADL. A SPIRIT diagram detailing the timing of enrolment, interventions and assessments is provided in figure 1.

Feasibility of recruitment and sample size

We conducted an a priori power analysis (using G*power, version 3.1.7) [26] that assumed a medium-to-large effect size based on the results of a previous RCT in the field of OT with an effect size of 0.76 [24]. The analysis indicated that a total sample size of 68 clients (34 in each group) would provide 80% power for detecting a difference, with an effect size of 0.7 for health-related QOL scores using a two-tailed test and an alpha level of 0.05. To compensate for client drop out, we will recruit 80 clients. We aim to finish this recruitment in 1 year.

Randomization

This study is designed as a single-blind RCT that will be reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement [27] for reporting clinical trials. Clients will be randomly assigned by blocked randomization (block size four) to the experimental or control groups. As the factors within the experimental and control groups affecting the outcome measures are homogeneous, randomization will be stratified by the disease group (cerebrovascular/musculoskeletal disease) and a visual analog scale for self-assessment of general health in EuroQol-5 Dimensions (EQ-5D) [EQ-VAS (high/low, boundary 50)] [28] will be used, resulting in four layers: 1. cerebrovascular disease and high EQ-VAS, 2. cerebrovascular disease and low EQ-VAS, 3. musculoskeletal disease and high EQ-VAS, and 4. musculoskeletal disease

and low EQ-VAS. Block order will be randomly assigned using computer-generated software (R. Ver. 3.2.1). Our statistician will create a block random pattern of each layer, but the grouping will be single-blinded. On the basis of the calculated random pattern, the assignment will be known to the occupational therapist. We intend to individually randomize patients in this research, and we use a dedicated process support application in the experimental group, but not in the control group. Therefore, there is almost no possibility of contamination between the two groups. The clients will be blinded to group allocation, although the therapists will be aware of the treatment group assigned. After the last outcome measurement point, each client will be asked to guess their assigned group.

Inclusion and exclusion criteria

Inclusion criteria for this study will be clients with cerebrovascular or musculoskeletal disease admitted to the recovery rehabilitation unit of the Harue Hospital, Fukui, Japan. Clients aged <50 years and >100 years at the time of their admission to the unit will be excluded from the study. In addition, clients whose Mini-Mental State Examination score is assessed as ≤23 points at their first OT appointment after admission to the unit will be excluded from the study [29]. The exclusion criteria are transfer of the patient to another unit, another hospital, or death.

Patient and Public Involvement statement

All recruited clients will need to provide written, informed consent. The clients will be not involved in the recruitment to and conduct of this study. We have designed the study to minimize client time and physical restrictions; all participants are free to withdraw from the study at any time. Structural evaluation on client's burden in RCTs will be not performed. We will inform the results to the applicants.

Procedure

Intervention

In the experimental and control groups, OT will be provided in accordance with the American Occupational Therapy Association guidelines [30]. The study intervention will be implemented by occupational therapists who have at least 200 work h of experience in delivering treatment according to client-centered OT. Moreover, therapists will be trained for at least 50 h on ACS-OT. The standard OT program will focus on the occupational performance of activities and be conducted individually with each client. Treatment will consist of 40–60-min sessions, conducted six times per week. The implementation period will be from admission to discharge.

Experimental group

In the experimental group, we used our own custom application program designed to run on a mobile device to control the following processes.

1. During the first session of OT, the therapist will assess the client's problems with ADL using the Canadian Occupational Performance Measure [31]. Based on the problems identified, activities that could be supported by OT will be identified.
2. During the second session, the client will perform the selected activities and will be invited to evaluate the activities using the challenge and skill levels assessment. The "challenge level" will be defined as the client's perception of the level of difficulty associated with the activity and will be rated on a seven-point scale from "very simple" (1) to "very difficult" (7). The "skill level" will be defined as the client's perception of their own skills in relation to the activity and will be rated on a seven-point scale from "not at all" (1) to "very skillful" (7) [32-33]. At that time, the therapist will clarify with the client regarding reasons for their challenge and skill level ratings.
3. Based on the client's and therapist's evaluations, the factors which make the client's occupational performance more difficult (challenge components, such as environment, execution time, and movement range required for activity) and factors that improve their occupational performance (skill components, such as frequency, range, distance, accuracy, and

dexterity) will be determined. In the experimental group, the compensation approach, such as environmental adjustment and use of technical aid, will be used for adjusting the challenge level.

4. Based on these components and traditional assessment and activity analysis, the occupational therapist will reconfigure the activity contents after adjusting the challenge–skill balance. The criteria for judging that the challenge–skill balance has been adjusted is defined in terms of the difference between the "challenge level" and "skill level" set by occupational therapist and client, which is 1 or less, respectively. For example, regarding activity on bathing, if the occupational therapist evaluates challenge level to 4, skill level to 5 and the client himself evaluates challenge level to 4, skill level to 4, we judge that it is adjusted. If the occupational therapist evaluates challenge level to 4, skill level to 4, and the client himself evaluates challenge level to 4, skill level to 2, it judges that it is not adjusted.
5. After the client has performed the adjusted activities, the client's challenge–skill levels will be re-evaluated. When the client's challenge–skill levels are determined to be balanced, interventions centered on the improvement of performance of the activities will commence. If the client's challenge–skill levels are not balanced, the activities will then be re-adjusted, and the intervention will start once the levels are balanced. The intervention will aim to improve the client's skill levels on the activities once their challenge–skill levels have been balanced.
6. This re-assessment process will occur at least once a week.

Control group

For the control group, the first and second sessions will be conducted similar to that conducted for the experimental group, except that the therapists will not be informed of the client's subjective perception of the challenge and skill levels for the activities. From the third session onwards, the therapists will simply assess the client's performance and conduct the therapy in a manner typical of OT, following the general guidelines for OT practice.

Outcomes

Outcomes will be measured at entry (pre) and discharge from the unit (post) and at 3 months afterwards (follow-up). The primary outcome measure will be subjective QOL. All outcomes to be measured are listed below:

Subjective quality of life (pre, post, and follow-up)

Ikigai-9 is a self-assessed psychological instrument for measuring an individual's mental state (reason for living; ikigai) and QOL [34]. It comprises nine items; a total score (9–45 points) and three subscale scores (of 15 points each) are calculated.

Health-related quality of life (pre, post, and follow-up)

Health-related QOL will be assessed using the EQ-5D. The EQ-5D defines health-related QOL with five dimensions: mobility, self-care, day-to-day activities, pain and discomfort, and anxiety or depression [28]. The EQ-5D also has a visual analog scale (EQ-VAS) that enables self-assessment on a scale from 0 (worst possible health) to 100 (best possible health).

Flow experience (pre and post)

Flow experience will be assessed using the Flow State Scale for Occupational Tasks [35], developed for clinical situations. Since the Flow state scale for occupational task in this study is to be carried out for occupational therapy in the recovery rehabilitation unit, this evaluation is not carried out at follow-up (after discharge). This consists of 14 items and three factors. The items were measured on a seven-point scale ranging from "strong disagreement" (1) to "strong agreement" (7), with possible scores ranging from 7 to 98.

Activities of daily living (pre and post)

ADL will be measured using the Functional Independence Measure (FIM) [36]. FIM is assessed by occupational therapist during admission to the recovery rehabilitation unit, and not implemented at follow-up. FIM is an 18-item, seven-level scale that uniformly assesses the severity of an

individual's disability and medical rehabilitation functional outcome. The range of values for FIM is from 18 (dependent) to 126 (fully independent).

Clinical global impression (post)

The Clinical Global Impression (CGI) rating scales are measures of overall treatment improvement. CGI is rated on a seven-point scale, with the severity of illness scale using a range of responses from 1 indicating "very much improved" to 7 indicating "very much worse" [37]. CGI is used for determining the minimally important change (MIC) [38] in the main outcome (QOL).

ACS implementation status for occupational therapy (post)

Evaluation of ACS implementation status will be conducted by the occupational therapists. This evaluation method was prepared for this research to verify whether the experimental process is feasible. This evaluation is rated on a seven-point scale from "very poor" (1) to "excellent" (7) and consists of the following three items: 1) Whether differences in recognition between the client and the therapist were confirmed, 2) whether differences in recognition between the client and the therapist were adjusted during OT, and 3) whether OT suitable for the client was provided. The occupational therapist will fill out this evaluation following each interventional session with a client.

Statistical analysis

All statistical analyses will be performed using SPSS Ver. 24.0 for Macintosh (SPSS, Chicago, IL, USA). Data will be de-identified and entered into Microsoft Excel 2016 and subsequently exported into SPSS software for analysis. The analysis will be performed by the statistician who will be blinded to the random group assignments. The chief researcher will have access to the final trial dataset. Baseline characteristics of the groups will be compared using chi-square and independent samples t-tests for the categorical variables. The Mann–Whitney U test will be used for assessing baseline continuous variables. Primary analysis for this study will be performed using intention to treat principles.

Generalized linear mixed model

Each continuous outcome variable will be analyzed using a generalized linear mixed model (GLMM) fitted with a maximum likelihood estimation. We will assign the following fixed effects: group (experimental or control group), time (pre, post, or 3-month follow-up), and the interaction of group and time. In addition, we will include the participants as a random effect. All participants who provided baseline data are included in the analysis. LMM is an appropriate statistical method for longitudinal design studies with missing data in clinical trials [39]. All confidence intervals will be provided with 95% margins. For all tests, a two-sided significance level of $p< 0.05$ will be used. Between-groups effect sizes will be calculated as standardized mean differences.

Minimal importance change

MIC for each outcome will be calculated using the anchor-based method [40]. The area under the receiver operating characteristic curve will identify the cut-off point on CGI scores that most optimally distinguishes between CGI scores of minimal improvement (1–3) and scores of no difference (4–7). The cut-off will be used to provide an MIC estimate that will maximize the Youden J statistic: sensitivity − (1–specificity) [41]. On the other hand, since there are few possibilities of deteriorating in the recovery rehabilitation unit, there is a possibility of adopting a method that uses MIC as each outcome mean value of the client who evaluated CGI as 3 (slightly improved) [42].

Cost-effectiveness

A cost-effectiveness analysis will be performed using the total cost and quality-adjusted life years (QALYs) based on the index value of EQ-5D. Incremental cost-effectiveness ratios (ICERs) will be calculated based on comparisons of the experimental and control groups. The total cost will be converted into US dollars using the average currency exchange rate at the time of data analysis. ICER will be estimated using the following equation:

$$ICER = [\mu Ce - \mu Cc]/[\mu Ee - \mu Ec]$$

where μC and μE represent the mean cost and mean QALY for the experimental and control groups, respectively. To account for uncertainty of ICER, the bootstrap method (1000 times) will be used for calculating mean values [43].

Ethics and dissemination

This protocol has been approved by the ethics review committee of the Tokyo Metropolitan University (No.17020).

Discussion

This research protocol proposal was prepared to examine the effect of ACS-OT on subjective QOL of clients in a recovery rehabilitation unit as an RCT. The process to be used in this study was devised based on the flow model and shares the perception of activities between the client and occupational therapist. Also, this process highlights the importance of provision of appropriate activities for clients. The client's perception of their challenge–skill balance is highly relevant to the degree of difficulty and occupational performance of activities provided by OT. We believe that understanding the client's subjective assessment of their activities according to their challenge–skill balance supports effective OT.

A previous RCT that used a similar protocol for older adults in an adult day program observed improvements in health-related QOL [24]. However, only one activity was examined and a follow-up period was not set. The current proposal will cover several activities such as toilet, bathing, cooking, shopping in which clients would require assistance during admission to a recovery rehabilitation unit. Furthermore, by setting a follow-up period, we will verify the continuity of the effect in addition to the direct effect of ACS-OT implementation. We hypothesize that ACS-OT will enhance the effects of positive emotions and self-affirmation by facilitating activities suitable for clients. As such, subjective QOL (according to the Ikigai-9) is the main

outcome. Importantly, this suggests that improvements in OT yield new findings on subjective QOL. In addition, using a GLMM, it will be possible to perform an analysis that considers individual differences as a random effect.

Study limitations

Subjective evaluations, such as subjective QOL, health-related QOL, and flow experience, are highly likely to result in measurement bias. To address this, we will adopt an RCT design and perform self-assessed outcome measurements. In addition, there is a blinding problem in this RCT as the investigators in this study are occupational therapists, and thus, it will be difficult to blind occupational therapists to their assignment and intervention method.

We will use a convenience sample from the recovery rehabilitation unit of a single hospital, which may not be representative of all clients in a recovery rehabilitation unit. This study will not include patients with acute or subacute diseases, outpatients, and clients who use community rehabilitation services. Therefore, our results cannot be generalized to these populations.

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Footnotes

Authors' contributions**:** IY conceived and designed the experiments. IY performed the experiments. IY and KH analyzed data. IY drafted the paper. KH and RK made further reviews as well as modifications. RK is also responsible for managing voluntarily reported adverse events from clients and other unintended effects of the intervention. All authors have read and approved the final manuscript.

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Competing interests statement**:** None declared.

Figure 1. SPIRIT diagram describing schedule of enrolment, interventions and assessments.

	Study Period					
	Enrolment	Baseline	Allocation	Post-allocation		Close-out
TIMEPOINT	0	0	0	Intervention	Discharge	3months
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation			X			
INTERVENTIONS:						
Experimental Group				←	→	
Control Group				←	→	
ASSESSMENTS:						
Baseline variables	X					
Ikigai-9		X			X	X
EQ-5D		X			X	X
Flow state scale for occupational task		X			X	
FIM		X			X	
CGI					X	
ACS implementation status					X*	

* ACS implementation status coverd the experimental group

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	p1 l-2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	p2 l11-12
	2b	All items from the World Health Organization Trial Registration Data Set	Contained in various parts throughout manuscript
Protocol version	3	Date and version identifier	p2 l11-12
Funding	4	Sources and types of financial, material, and other support	p19 l13-14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	p1 l4-12, p19 l3-7
	5b	Name and contact information for the trial sponsor	p1 l4-12
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	p19 l13-14

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	p4 l1-p5 l17
	6b	Explanation for choice of comparators	p5 l20
Objectives	7	Specific objectives or hypotheses	p5 l13-17
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	p6 l18-19
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	p7 l11-12
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	p7 l10-16
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	p7 l25-p9 l26
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	p7 l15-16
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	p8 l10-11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	p9 l1-3

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	p10 l2-p11 l16
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	p6 l9-15
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	p6 l14-15
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	p6 l19-p7 l6
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	p7 l2-5
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	p7 l2-6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	p7 l6-8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	p7 l6-8

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	p10 l3-4
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	p7 l20-21, p12 l6-8
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	p11 l20-21
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	p12 l2-10
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	p12 l11-p13 l4
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	p12 l6-8

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a Low risk intervention
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a Low risk intervention
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	p19 l5-6

Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a Low risk intervention
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	p13 l6-8
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	No changes anticipated
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	p7 l19-23
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	p11 l19-23
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	p19 l16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	p11 l22-23
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	p7 l22-23
	31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Will be available in Japanese if wanted
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Effect of adjusting the challenge–skill balance for occupational therapy: study protocol for a randomized controlled trial

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Effect of adjusting the challenge–skill balance for occupational therapy: study protocol for a randomized controlled trial

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Abstract

Introduction: Occupational therapy (OT) is defined as the promotion of client health and well-being through a client-centered practice. However, there is a tendency to rely on the therapist's experiences and values, and there is a difference between the client's and therapist's perceptions regarding the current activity that the client is engaged in. In previous studies that have applied "flow," activities supported by OT in elderly people were analyzed, indicating a difference in recognition. Therefore, we thought that more effective OT could be implemented by adjusting the challenge–skill balance, and we invented a novel process termed as adjusting the challenge–skill balance for OT (ACS-OT). The purpose of this study is to verify the effect of ACS-OT on clients in the recovery rehabilitation

unit and to prepare a protocol for randomized control trial (RCT) implementation.

Method and Analysis: This single-blind RCT will recruit 80 50–99-year-old clients admitted to the recovery rehabilitation unit who meet eligibility criteria. Clients will be randomly allocated to receive ACS-OT or standard OT. Both interventions will be performed during the clients' residence at the unit. The primary outcome measure will be subjective quality of life and will be measured at entry into (pre) and at discharge from (post) the unit and at 3 months afterwards (follow-up). Outcomes will be analyzed using a generalized linear mixed model fitted with a maximum likelihood estimation.

Ethics and Dissemination: This protocol has been approved by the ethics review committee of the Tokyo Metropolitan University (No.17020). Results of this trial will be submitted for publication in a peer-reviewed journal.

Registration: University Hospital Medical Information Network 2017 UMIN000029505. Registered on October 11, 2017.

Strengths and limitations of this study

- We designed a RCT to verify if ACS-OT is effective in improving subjective quality of life.
- Stratified randomization is responsible for homogeneous assignment of experimental group and control group.
- Outcomes analysis using clients as random effect by linear mixed model.
- It is impossible to blind the therapists because of the nature of intervention in the OT process.
- Our study results will be limited to the recovery rehabilitation unit.

Background

Rehabilitation aims to maximally promote the process of recovery from injury, illness, or disease, supporting the client to reach a normal condition. An occupational therapist is a health professional who aims to support the client to return to independence, meaning, satisfaction in all aspects of people's lives. Likewise, occupational therapy (OT) is defined as a profession that promotes clients' health and well-being through a client-centered practice. In many countries, client-centered practice is the basis for OT; this practice contributes to the realization of meaningful activities for the client [1-5], which are defined as familiar activities which aligns with an individual's pursuit of valued developmental goals to maintain a personally meaningful lifestyle [6-7]. In saying this, within processes related to a client-centered practice, there is a tendency to rely on the therapist's experience and values. There is a difference between the client's and therapist's perceptions regarding the activity engaged in by the client [8-9]. To support the activity *desired* by the client, it is necessary to determine the client's evaluation of the activity in a form that the client and the therapist can easily share. In addition, deterioration of the client's health and physical and mental functions, and loss of social role often causes decreased motivation to perform these activities [10-11]. Therefore, in OT, it is necessary for clients and therapists to easily share the meaning of activity and to provide support that facilitates positive client mental state. To reflect this in our research, we applied the concept of "flow," which captures the psychological state of a particular activity. Flow is defined as "the state in which people are so involved in an activity that nothing else seems to matter at the time; the experience is so enjoyable that people will do it even at great cost, for the sheer sake of doing it" [12]. With regards to research on flow in the OT field, there have been reports on improved happiness, self-esteem, work productivity, and subjective well-being level [13-18]. According to Csikszentmihalyi [12], flow can be explained according to the balance between challenge and skills, i.e., the "flow model." Flow is experienced when an individual's perception of the difficulty associated with an activity is balanced with their level of skill. Conversely, activities in which the individual's skill is perceived to be too close to the difficulty associated with the activity leads to

boredom. Similarly, conditions of low-perceived skill in a high-perceived challenge result anxiety, whereas conditions of low-perceived skill and low-perceived challenge result in apathy. Several cross-sectional studies using the flow model have been reported [19-23]. In our previous research using the flow model to shape the OT practice, although the occupational therapist judged the activity to be suitable for the clients, clients themselves felt that the activity made them feel anxious, bored, and apathetic [9].

We believe that more effective OT and realization of meaningful activities for clients could be provided by adjusting the challenge–skill balance. Therefore, we invented a new process called adjusting the challenge–skill balance for OT (ACS-OT). A randomized controlled trial (RCT) conducted using ACS-OT for the elderly in an adult day program showed improvements in health-related quality of life (QOL) [24]. However, this previous research only tested one activity, which limits the generalization of the effect of ACS-OT on the larger population and to different activities. Therefore, we propose to examine the effect of ACS-OT on clients in the recovery phase who need timely support on activities of daily living (ADL) and occupational performance necessary to return to their home life. To test this, we plan to employ ACS-OT in the recovery rehabilitation unit of Harue Hospital, Fukui, Japan, and to determine a protocol for RCT implementation.

Method and Analysis

This study was designed as a single-blind RCT, this protocol will be reported according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement [25] and the results of this trial will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines [26]. This study is planned to compare ACS-OT with standard occupational therapy (control). To minimize heterogeneity of the client sample, we will test clients aged 50–99 years old admitted to the recovery rehabilitation unit. This age range was chosen as the average age of patients admitted is 76.8 ± 12.7 years, and we extended the target age range to ± 2 standard deviations. As discussed in a previous review [27], this study represents the practice of client-centered

OT, focusing on ADL and occupational performance. To determine if ACS-OT could be effective with various diseases, we targeted cerebrovascular and musculoskeletal disease, which are the main diseases observed at our recovery rehabilitation unit. The average admission period in this unit is 8–10 weeks for cerebrovascular disease and 6–8 weeks for musculoskeletal disease. The intervention period in this study is set to 6–10 weeks, and the number of interventions would be 36–60. The primary outcome measure will be change in subjective QOL, which will be compared between the experimental and control groups. The secondary outcome measure will be change in flow experience, health-related QOL, and performance of ADL. A SPIRIT diagram detailing the timing of enrolment, interventions and assessments is provided in figure 1.

Feasibility of recruitment and sample size

We conducted an a priori power analysis (using G*power, version 3.1.7) [28] that assumed a medium-to-large effect size based on the results of a previous RCT in the field of OT with an effect size of 0.76 [24]. The analysis indicated that a total sample size of 68 clients (34 in each group) would provide 80% power for detecting a difference, with an effect size of 0.7 for health-related QOL scores using a two-tailed test and an alpha level of 0.05. To compensate for client drop out, we will recruit 80 clients. We aim to finish this recruitment in 1 year.

Randomization

Clients will be randomly assigned by blocked randomization (block size four) to the experimental or control groups. As the factors within the experimental and control groups affecting the outcome measures are homogeneous, randomization will be stratified by the disease group (cerebrovascular/musculoskeletal disease) and a visual analog scale for self-assessment of general health in EuroQol-5 Dimensions (EQ-5D) [EQ-VAS (high/low, boundary 50)] [29] will be used, resulting in four layers: 1. cerebrovascular disease and high EQ-VAS, 2. cerebrovascular disease and low EQ-VAS, 3. musculoskeletal disease and high EQ-VAS, and 4. musculoskeletal disease and low

EQ-VAS. Block order will be randomly assigned using computer-generated software (R. Ver. 3.2.1). Our statistician will create a block random pattern of each layer, but the grouping will be single-blinded. On the basis of the calculated random pattern, the assignment will be known to the occupational therapist. We intend to individually randomize patients in this research, and we use a dedicated process support application in the experimental group, but not in the control group. Therefore, there is almost no possibility of contamination between the two groups. The clients will be blinded to group allocation, although the therapists will be aware of the treatment group assigned. After the last outcome measurement point, each client will be asked to guess their assigned group.

Inclusion and exclusion criteria

Inclusion criteria for this study will be clients with cerebrovascular or musculoskeletal disease admitted to the recovery rehabilitation unit of the Harue Hospital, Fukui, Japan. Clients aged <50 years and >100 years at the time of their admission to the unit will be excluded from the study. In addition, clients whose Mini-Mental State Examination score is assessed as ≤23 points at their first OT appointment after admission to the unit will be excluded from the study [30]. The exclusion criteria are transfer of the patient to another unit, another hospital, or death.

Patient and Public Involvement statement

The clients will be not involved in the recruitment to and conduct of this study. We have designed the study to minimize client time and physical restrictions; all participants are free to withdraw from the study at any time. Structural evaluation on client's burden in RCTs will be not performed. We will inform the results to the applicants.

Procedure

Intervention

In the experimental and control groups, OT will be provided in accordance with the American Occupational Therapy Association guidelines [31]. The study intervention will be implemented by occupational therapists who have at least 200 work h of experience in delivering treatment according to client-centered OT. Moreover, therapists will be trained for at least 50 h on ACS-OT. The standard OT program will focus on the occupational performance of activities and be conducted individually with each client. Treatment will consist of 40–60-min sessions, conducted six times per week. The implementation period will be from admission to discharge.

Experimental group

In the experimental group, we used our own custom application program designed to run on a mobile device to control the following processes.

1. During the first session of OT, the therapist will assess the client's problems with ADL using the Canadian Occupational Performance Measure [32]. Based on the problems identified, activities that could be supported by OT will be identified.
2. During the second session, the client will perform the selected activities and will be invited to evaluate the activities using the challenge and skill levels assessment. The "challenge level" will be defined as the client's perception of the level of difficulty associated with the activity and will be rated on a seven-point scale from "very simple" (1) to "very difficult" (7). The "skill level" will be defined as the client's perception of their own skills in relation to the activity and will be rated on a seven-point scale from "not at all" (1) to "very skillful" (7) [33-34]. At that time, the therapist will clarify with the client regarding reasons for their challenge and skill level ratings.
3. Based on the client's and therapist's evaluations, the factors which make the client's occupational performance more difficult (challenge components, such as environment, execution time, and movement range required for activity) and factors that improve their occupational performance (skill components, such as frequency, range, distance, accuracy, and

dexterity) will be determined. In the experimental group, the compensation approach, such as environmental adjustment and use of technical aid, will be used for adjusting the challenge level.

4. Based on these components and traditional assessment and activity analysis, the occupational therapist will reconfigure the activity contents after adjusting the challenge–skill balance. The criteria for judging that the challenge–skill balance has been adjusted is defined in terms of the difference between the "challenge level" and "skill level" set by occupational therapist and client, which is 1 or less, respectively. For example, regarding activity on bathing, if the occupational therapist evaluates challenge level to 4, skill level to 5 and the client himself evaluates challenge level to 4, skill level to 4, we judge that it is adjusted. If the occupational therapist evaluates challenge level to 4, skill level to 4, and the client himself evaluates challenge level to 4, skill level to 2, it judges that it is not adjusted.
5. After the client has performed the adjusted activities, the client's challenge–skill levels will be re-evaluated. When the client's challenge–skill levels are determined to be balanced, interventions centered on the improvement of performance of the activities will commence. If the client's challenge–skill levels are not balanced, the activities will then be re-adjusted, and the intervention will start once the levels are balanced. The intervention will aim to improve the client's skill levels on the activities once their challenge–skill levels have been balanced.
6. This re-assessment process will occur at least once a week.

Control group

For the control group, the first and second sessions will be conducted similar to that conducted for the experimental group, except that the therapists will not be informed of the client's subjective perception of the challenge and skill levels for the activities. From the third session onwards, the therapists will simply assess the client's performance and conduct the therapy in a manner typical of OT, following the general guidelines for OT practice.

Outcomes

Outcomes will be measured at entry (pre) and discharge from the unit (post) and at 3 months afterwards (follow-up). The primary outcome measure will be subjective QOL. All outcomes to be measured are listed below:

Subjective quality of life (pre, post, and follow-up)

Ikigai-9 is a self-assessed psychological instrument for measuring an individual's mental state (reason for living; ikigai) and QOL [35]. It comprises nine items; a total score (9–45 points) and three subscale scores (of 15 points each) are calculated.

Health-related quality of life (pre, post, and follow-up)

Health-related QOL will be assessed using the EQ-5D. The EQ-5D defines health-related QOL with five dimensions: mobility, self-care, day-to-day activities, pain and discomfort, and anxiety or depression [29]. The EQ-5D also has a visual analog scale (EQ-VAS) that enables self-assessment on a scale from 0 (worst possible health) to 100 (best possible health).

Flow experience (pre and post)

Flow experience will be assessed using the Flow State Scale for Occupational Tasks [36], developed for clinical situations. Since the Flow state scale for occupational task in this study is to be carried out for occupational therapy in the recovery rehabilitation unit, this evaluation is not carried out at follow-up (after discharge). This consists of 14 items and three factors. The items were measured on a seven-point scale ranging from "strong disagreement" (1) to "strong agreement" (7), with possible scores ranging from 7 to 98.

Activities of daily living (pre and post)

ADL will be measured using the Functional Independence Measure (FIM) [37]. FIM is assessed by occupational therapist during admission to the recovery rehabilitation unit, and not implemented at follow-up. FIM is an 18-item, seven-level scale that uniformly assesses the severity of an

individual's disability and medical rehabilitation functional outcome. The range of values for FIM is from 18 (dependent) to 126 (fully independent).

Clinical global impression (post)

The Clinical Global Impression (CGI) rating scales are measures of overall treatment improvement. CGI is rated on a seven-point scale, with the severity of illness scale using a range of responses from 1 indicating "very much improved" to 7 indicating "very much worse" [38]. CGI is used for determining the minimally important change (MIC) [39] in the main outcome (QOL).

ACS implementation status for occupational therapy (post)

Evaluation of ACS implementation status will be conducted by the occupational therapists. This evaluation method was prepared for this research to verify whether the experimental process is feasible. This evaluation is rated on a seven-point scale from "very poor" (1) to "excellent" (7) and consists of the following three items: 1) Whether differences in recognition between the client and the therapist were confirmed, 2) whether differences in recognition between the client and the therapist were adjusted during OT, and 3) whether OT suitable for the client was provided. The occupational therapist will fill out this evaluation following each interventional session with a client.

Statistical analysis

All statistical analyses will be performed using SPSS Ver. 24.0 for Macintosh (SPSS, Chicago, IL, USA). Data will be de-identified and entered into Microsoft Excel 2016 and subsequently exported into SPSS software for analysis. The analysis will be performed by the statistician who will be blinded to the random group assignments. The chief researcher will have access to the final trial dataset. Baseline characteristics of the groups will be compared using chi-square and independent samples t-tests for the categorical variables. The Mann–Whitney U test will be used for assessing baseline continuous variables. Primary analysis for this study will be performed using intention to treat principles.

Generalized linear mixed model

Each continuous outcome variable will be analyzed using a generalized linear mixed model (GLMM) fitted with a maximum likelihood estimation. We will assign the following fixed effects: group (experimental or control group), time (pre, post, or 3-month follow-up), and the interaction of group and time. In addition, we will include the participants as a random effect. All participants who provided baseline data are included in the analysis. LMM is an appropriate statistical method for longitudinal design studies with missing data in clinical trials [40]. All confidence intervals will be provided with 95% margins. For all tests, a two-sided significance level of $p< 0.05$ will be used. Between-groups effect sizes will be calculated as standardized mean differences.

Minimal importance change

MIC for each outcome will be calculated using the anchor-based method [41]. The area under the receiver operating characteristic curve will identify the cut-off point on CGI scores that most optimally distinguishes between CGI scores of minimal improvement (1–3) and scores of no difference (4–7). The cut-off will be used to provide an MIC estimate that will maximize the Youden J statistic: sensitivity − (1–specificity) [42]. On the other hand, since there are few possibilities of deteriorating in the recovery rehabilitation unit, there is a possibility of adopting a method that uses MIC as each outcome mean value of the client who evaluated CGI as 3 (slightly improved) [43].

Cost-effectiveness

A cost-effectiveness analysis will be performed using the total cost and quality-adjusted life years (QALYs) based on the index value of EQ-5D. Incremental cost-effectiveness ratios (ICERs) will be calculated based on comparisons of the experimental and control groups. The total cost will be converted into US dollars using the average currency exchange rate at the time of data analysis. ICER will be estimated using the following equation:

$$ICER = [\mu Ce - \mu Cc]/[\mu Ee - \mu Ec]$$

where μC and μE represent the mean cost and mean QALY for the experimental and control groups, respectively. To account for uncertainty of ICER, the bootstrap method (1000 times) will be used for calculating mean values [44].

Ethics and dissemination

All recruited clients will need to provide written, informed consent. This protocol has been approved by the ethics review committee of the Tokyo Metropolitan University (No.17020). The study results will be disseminated through peer-reviewed publications.

Discussion

This research protocol proposal was prepared to examine the effect of ACS-OT on subjective QOL of clients in a recovery rehabilitation unit as an RCT. The process to be used in this study was devised based on the flow model and shares the perception of activities between the client and occupational therapist. Also, this process highlights the importance of provision of appropriate activities for clients. The client's perception of their challenge–skill balance is highly relevant to the degree of difficulty and occupational performance of activities provided by OT. We believe that understanding the client's subjective assessment of their activities according to their challenge–skill balance supports effective OT.

A previous RCT that used a similar protocol for older adults in an adult day program observed improvements in health-related QOL [24]. However, only one activity was examined and a follow-up period was not set. The current proposal will cover several activities such as toilet, bathing, cooking, shopping in which clients would require assistance during admission to a recovery rehabilitation unit. Furthermore, by setting a follow-up period, we will verify the continuity of the effect in addition to the direct effect of ACS-OT implementation. We hypothesize that ACS-OT will enhance the effects of positive emotions and self-affirmation by facilitating activities suitable for clients. As such, subjective QOL (according to the Ikigai-9) is the main outcome. Importantly, this

suggests that improvements in OT yield new findings on subjective QOL. In addition, using a GLMM, it will be possible to perform an analysis that considers individual differences as a random effect.

Study limitations

Subjective evaluations, such as subjective QOL, health-related QOL, and flow experience, are highly likely to result in measurement bias. To address this, we will adopt an RCT design and perform self-assessed outcome measurements. In addition, there is a blinding problem in this RCT as the investigators in this study are occupational therapists, and thus, it will be difficult to blind occupational therapists to their assignment and intervention method.

We will use a convenience sample from the recovery rehabilitation unit of a single hospital, which may not be representative of all clients in a recovery rehabilitation unit. This study will not include patients with acute or subacute diseases, outpatients, and clients who use community rehabilitation services. Therefore, our results cannot be generalized to these populations.

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Footnotes

Authors' contributions**:** IY conceived and designed the experiments. IY performed the experiments. IY and KH analyzed data. IY drafted the paper. KH and RK made further reviews as well as modifications. RK is also responsible for managing voluntarily reported adverse events from clients and other unintended effects of the intervention. All authors have read and approved the final manuscript.

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Competing interests statement**:** None declared.

1

Figure 1. SPIRIT diagram describing schedule of enrolment, interventions and assessments

Figure 1. SPIRIT diagram describing schedule of enrolment, interventions and assessments.

	Study Period					
	Enrolment	Baseline	Allocation	Post-allocation		Close-out
TIMEPOINT	0	0	0	Intervention	Discharge	3months
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation			X			
INTERVENTIONS:						
Experimental Group				←	→	
Control Group				←	→	
ASSESSMENTS:						
Baseline variables	X					
Ikigai-9		X			X	X
EQ-5D		X			X	X
Flow state scale for occupational task		X			X	
FIM		X			X	
CGI					X	
ACS implementation status					X*	

* ACS implementation status coverd the experimental group

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	p1 l-2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	p2 l11-12
	2b	All items from the World Health Organization Trial Registration Data Set	Contained in various parts throughout manuscript
Protocol version	3	Date and version identifier	p2 l11-12
Funding	4	Sources and types of financial, material, and other support	p19 l13-14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	p1 l4-12, p19 l3-7
	5b	Name and contact information for the trial sponsor	p1 l4-12
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	p19 l13-14

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	p4 l1-p5 l17
	6b	Explanation for choice of comparators	p5 l20
Objectives	7	Specific objectives or hypotheses	p5 l13-17
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	p6 l18-19
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	p7 l11-12
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	p7 l10-16
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	p7 l25-p9 l26
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	p7 l15-16
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	p8 l10-11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	p9 l1-3

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	p10 l2-p11 l16
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	p6 l9-15
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	p6 l14-15
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	p6 l19-p7 l6
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	p7 l2-5
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	p7 l2-6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	p7 l6-8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	p7 l6-8

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	p10 l3-4
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	p7 l20-21, p12 l6-8
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	p11 l20-21
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	p12 l2-10
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	p12 l11-p13 l4
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	p12 l6-8

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a Low risk intervention
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a Low risk intervention
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	p19 l5-6

Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a Low risk intervention
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	p13 l6-8
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	No changes anticipated
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	p7 l19-23
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	p11 l19-23
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	p19 l16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	p11 l22-23
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	p7 l22-23
	31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Will be available in Japanese if wanted
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.