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Study protocol for a randomised controlled trial evaluating effectiveness of Strengths Model Case Management (SMCM) with Chinese mental health service users in Hong Kong

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ABSTRACT

Introduction: Strengths-based approaches, different from traditional treatments that largely reply on medication, mobilize individual and environmental resources can facilitate the recovery of people with mental illnesses. Strengths Model Case Management (SMCM), developed by the University of Kansas, offers a structured and innovative intervention. As the evidence for the effectiveness of strengths-based interventions come from Western studies and the studies lack methodological rigor or failed to assure fidelity to the model, we aim to conduct a randomized controlled trial to test the effectiveness of SMCM for individuals with mental illnesses in Hong Kong.

Methods and analysis: This is a randomised controlled trial adopting SMCM. Based on a medium intervention effect (Cohen's d = .60) and the possibility of missing data at 6 and 12 months, 210 service users aged 18 or above will be recruited from community centres for mental wellness after screening for eligibility. They will then be randomly assigned to SMCM groups (intervention) or SMILE groups (control) in a 1:1 ratio. The SMCM groups will receive strengths model intervention from case workers to help them identify their individual and environmental strengths and set goals to facilitate their recovery whereas the SMILE groups will receive generic, recovery-oriented care from case workers with an attention placebo. The effectiveness of the SMCM will be compared between the two groups of service user participants with outcomes including recovery, state of hope, level of symptoms, community integration, mattering, working alliance, and goals attainment at baseline, 6 and 12 months after recruitment. Functional outcomes such as employment and hospitalization will also be assessed. At the same time, data on working alliance and goals attainment will be collected from individual case workers. Qualitative evaluation will be conducted to identify the therapeutic ingredients and conditions leading to positive outcomes. Outcome assessors will be blinded to group allocation.

Ethics and dissemination: Ethical approval from the Human Research Ethics Committee at the University of Hong Kong has been obtained (HRECNCF: EA1703078). The results will be disseminated to service users and their families via the media, to healthcare professionals via professional training and meetings, and to researchers via conferences and publications.

Trial registration number:

Australian New Zealand Clinical Trials Registry (ACTRN) 12617001435370.

Article summary

Strengths and limitations of this study:

- First randomised controlled trial that adopts a rigorous mixed-methods design to assess the effectiveness of SMCM among community mental health service users.
- Fidelity or integrity of the SMCM intervention will be monitored to explore its effects on service users' outcomes.
- Evidence of implementing SMCM in a Chinese community will be established.
- Key therapeutic ingredients of SMCM will be identified.
- The baseline level of recovery and functional outcomes may be high, which may lead to potential ceiling effects for detecting the SMCM effectiveness.

Keywords: Mental Health, Clinical Trial-Therapeutics, Protocols & Guidelines-Health Services Administration and Management

Word count: 3914

INTRODUCTION

Common mental disorders (CMD) such as depression and anxiety are highly prevalent in the population globally. It is estimated that over 300 million people experience depression worldwide.[1] A population-based study, Hong Kong Mental Morbidity Survey 2010-2013, reported that 13.3% and 2.5% of adults aged 16-75 years were diagnosed with CMD,[2] and psychotic disorders,[3] respectively. The consequences of CMD can be reflected in the results of the 2010 Global Burden of Diseases, Injuries, and Risk Factors Study (GBD 2010)[4] which reported that bipolar disorder and schizophrenia accounted for 7.0% and 7.4% of disability adjusted life years (DALY), respectively. In addition, the global costs of mental illnesses were estimated at US$2.5 trillion in 2010 and is set to more than double to US$6 trillion by 2030.[5] Mental illnesses not only affect the physical and psychological health of the individuals concerned, but also their family, caregivers, and friends. Therefore, better treatment and planning of care are essential to promote recovery from mental illnesses and improve outcomes.

Traditional treatments for mental illnesses primarily consist in medication.[6] However, mental illnesses are often long lasting and recurrent so taking medication alone may not be sufficient to achieve personal recovery which refers to the process of individual psychological adaptation to a disorder and addressing functional impairment.[7] With the proliferation of positive psychology advocated by Seligman,[8] more empirical studies focus on strengths of character which defined as "positive traits reflected in thoughts, feelings, and behaviors" [9] (p. 603) and positive experiences such as life satisfaction.[9] In recent years, more researchers advocated strengths-based approaches which mobilize individual and environmental resources that can facilitate recovery among people with mental illnesses.[10,11] Strengths model case management (SMCM) and its related practices, such as field mentoring, have gained increasing favor among practitioners since the 1980s.[12,13]

Conceptual framework: Kansas model, Strengths Model Case Management (SMCM)

Strengths model case management (SMCM) was developed by Rapp and Goscha from the University of Kansas (KU).[11,12] The Kansas model of SMCM aims to enhance recovery through instilling hope and empowering the choices and autonomy of service users, rather than focusing on deficits. Case management refers to the process of assessing needs, implementing a service plan, and monitoring progress to bring about positive outcomes.[14,15]

SMCM consists of three main core elements, including strengths assessment, personal recovery plan and group supervision. The strengths assessment is used to appraise the service users' strengths, niches, and other attributes such as hope, self-efficacy, and the resources available in the family and community, while the personal recovery plan uses the information obtained from the strengths assessment to derive a plan which consists of recovery goals that are meaningful for service users. Co-construction of recovery goals between service users and case workers can be challenging[16] so the steps towards achieving a goal should be small, specific, and measurable. Group supervision aims to provide a supportive environment for case workers to help service users achieve the goals they identify.

SMCM is guided by six major principles: (1) people with mental illnesses have the capacity to recover, reclaim, and transform their life; (2) the focus is on the strengths of individuals; (3) the community is perceived as an oasis of resources; (4) the client is the director of the helping process; (5) the worker-client relationship is essential; and (6) the primary setting of the work is the community.[12] In addition, SMCM lays emphasis on three themes. First, case workers should be creative about how to help each service user achieve a life that brings purpose, meaning, and a valued identity. Second, SMCM does not neglect the problems and impediments that service users are facing. Instead, problems and obstacles are perceived within the context of the goals that the service users desire to achieve. Third, SMCM is not only about a change in clinical practice, but it also requires the transformation of our care systems such as policies and the way we communicate with each other to best support service users in finding niches within their community in which they can thrive. Figure 1 shows the important concepts of the SMCM framework.

[INSERT Figure 1]

Most studies evaluating the effectiveness of SMCM in helping people with mental illnesses reported positive outcomes in many areas such as re-hospitalization, housing, employment, social support, family burden, and symptoms.[10,17-24] Similarly, in a recent review,[25] the results showed that the benefits associated with the strengths-based approach included the reduction of the duration of stay in the hospital, an increase in service satisfaction, an improvement of general attitudes towards recovery-relevant dimensions (e.g., self-efficacy and

sense of hope), an improvement of employment and educational outcomes, an increase in the utilization of general services, and an increase in job satisfaction as well as morale among mental health professionals. SMCM offers a promising alternative to traditional approaches.

Nevertheless, as the majority of studies about SMCM have been conducted in the Western context, its use and outcomes lack cultural sensitivity. The current study will provide an optimal opportunity to investigate SMCM's cultural (e.g., under the influence of Taoism, Chinese people tend to be more reserved to state their strengths and successes) and structural (e.g., the caseload sizes, the ratio of supervisor-to-case manager, and so on) compatibility and to understand how SMCM can be best implemented in community mental health settings such as Integrated Community Centres for Mental Wellness, and Integrated Services Centre. Furthermore, reviews of the existing literature indicate that there are limitations to the existing studies. First, among 11 empirical studies[17,19-21,24,26-31] which have investigated the effectiveness of SMCM in mental healthcare settings, only a single study used a randomized controlled trial (RCT) design which is considered to be the gold standard[32] in research and other studies used either secondary data analyses, quasi-experimental with a pre- and post- design, or between-group comparison. Second, those RCTs on so-called "strengths-based interventions" were all conducted prior to the year 2000. Furthermore, none of the studies used fidelity assessment to ensure that the intervention group was actually using the strengths model.[25] Next, the results from recent studies showed that SMCM fidelity affects intervention outcomes across service sites, with high-fidelity SMCM associated with lower rates of psychiatric hospitalization and higher employment rates.[31] However, little is known about the important constituent of the strengths model approach. Finally, the conceptualization of strengths is culturally defined through linguistics, metaphors, icons, and folklore traditions.[33] Therefore, examining the cultural responsiveness of SMCM before implementing it in a Chinese (or, more broadly, Asian) context is of paramount importance.[34]

Study objectives

Building on the experience of conducting an earlier trial using non-randomised design[35] in residential setting, the primary objective of the present study is to assess the effectiveness of SMCM when implemented among service users at Integrated Community Centres for Mental Wellness (ICCMWs) in Hong Kong, using a randomised controlled trial (RCT) design.

Specifically, we hypothesize that service users in the high-fidelity SMCM group will experience higher levels of personal recovery, as well as symptoms reduction, improved hope, community integration, mattering, working alliance, and goals attainment, relative to their counterparts in a control group which incorporates an attention placebo. The second objective is to evaluate the fidelity features of SMCM implementation and major therapeutic ingredients that have effects on service users' outcomes.

METHODS

Study design and setting

The study will take the form of a multi-centred RCT to examine the effectiveness of SMCM for service users with mental illnesses. It will consist of two arms: an SMCM intervention group and a control group (called 'SMILE' group; it is not an acronym). The service users in both arms will be recruited from the ICCMWs of three non-governmental organizations. To achieve diversity of the study samples, the NGOs joining the present study are located in different districts in Hong Kong. Service users attending ICCMWs are individuals with either suspected mental health problems or diagnosed mental illnesses.

Sample size and statistical power

We performed Monte Carlo simulations to estimate the required sample size by using the methods recommended by Muthén and Muthén.[36] We assumed a medium effect size (Cohen's *d* = .6) for the slope (change rate) difference of the primary outcome measure (a mean slope difference between the intervention and control groups) based on previous empirical studies. We assumed 15% and 30% missing data at 6 months and 12 months, respectively.[25] A total of 210 service users (n = 105 per group) will be required for a statistical power of .80 to detect a medium effect with the amount of missing data taken into consideration.

Participants

We will recruit a total of 210 service users from three ICCMWs. Upon the arrival of the service users, a trained case worker will do the recruitment. He/she will be responsible for screening the eligibility of service users based on the inclusion and exclusion criteria. The inclusion criteria include:

(i) being a service user of mental health services in ICCMWs;

(ii) being aged 18 or above;

(iii) being Chinese; the ability to read Chinese and speak Cantonese;

(iv) being diagnosed with mental illness, including major depressive disorders, anxiety disorder, bipolar disorder, and psychotic disorders, by a psychiatrist; and

(v) the ability to provide written informed consent to join the study and willingness to be allocated to either group (SMCM vs. SMILE).

On the other hand, the exclusion criteria are those service users who are:

(i) likely to engage in immediate risk behavior, such as suicide and/or violence; and/or

(ii) affected by overt psychotic symptoms and unable to sustain a meaningful conversation for more than 10 minutes as identified by case workers. Incentives in the form of supermarket coupons (worth HK$50) will be given to the service users at all three time points, as compensation for participating in the study.

Recruitment of Case workers

The case workers responsible for the delivery of SMCM intervention are ICCMWs staff (e.g., registered social worker, program worker, occupational therapist, nurse). They must have received prior training on SMCM provided by KU and participate in ongoing group supervision (see *Intervention groups* subsection).

Randomization

After screening their eligibility, all service users will be asked to complete a face-to-face baseline questionnaire (T_0). The case worker will contact the research team to obtain group allocation information and participants will be randomly allocated to either the SMCM or SMILE group in a 1:1 ratio, according to a pre-determined randomization list generated by an online randomization program (www.randomization.com). Block randomization will be performed to reduce bias and achieve balance in allocating participants into the intervention and control groups. Rolling enrolment will be used.

Participants with the group assignment will then be followed up by case workers using the SMCM or SMILE protocol and will be asked again to complete the same set of

questionnaires at 6 months (T_1) and 12 months (T_2). Service user participants can withdraw from the study at any time. The case workers and service users will not be blind to the group allocation, but the trained assessors who are peer researchers, will be blind to such information. In order to minimize contamination, case workers in the SMILE group will not be provided any of the tools related to SMCM (e.g., Strengths Assessment, Personal Recovery Plan), or receive any strengths-based supervision. Figure 2 shows the CONSORT diagram which illustrates the flow of participants throughout the research process.

[INSERT Figure 2]

Intervention groups: SMCM group

The service user participants allocated to the SMCM group will receive individual sessions of about 30 minutes every fortnight. The SMCM intervention can only be delivered by case workers who previously received training provided by KU. Case workers and supervisors will attend ongoing group supervision led by Goscha (SMCM's author) monthly via Skype. The Strengths Assessment and Personal Recovery Plan developed by the KU team will be used to guide the intervention sessions. During the intervention, the case workers will help the service users identify recovery goals that are meaningful to them and workers will attend weekly strengths-based supervision run at the ICCMWs. The Fidelity Scale of the service unit will be used every 6-month to monitor if these high-fidelity activities take place as expected. A leadership team will be established in each ICCMW to oversee the activities.

Control groups: SMILE group

Service users in the SMILE control group will receive generic intervention (i.e., treatment as usual) which includes recovery groups, medical appointments, leisure/hobby groups, general community activities. Case workers will have contact with service users fortnightly which will serve as the attention placebo. Table 1 summarizes the key characteristics of the SMCM intervention and SMILE control groups.

[INSERT Table 1]

To ensure the integrity of the intervention used in SMCM and SMILE groups, as well as the adherence to the model, two raters with a thorough understanding of SMCM will closely monitor the intervention by using the Fidelity Scale at 1 (baseline), 6 and 12 months after the intervention starts. The fidelity data will be collected through interviews with staff and service users, site observations, and reviews of the SMCM tools and charts. SMCM teams will achieve an overall fidelity score of 36 on the Fidelity Scale including an average rating of 4 out of 5 in each of the three core areas, namely structure, supervision/supervisor, and clinical/service, of the scale.

Patient and Public Involvement

Given the increasing importance of the role played by patients and public involvement (PPI) in research and the study objectives which aim to examine the effectiveness of SMCM, we involved the service users when we conducted a pilot study in September 2017. Three service users from each ICCMW (i.e., a total of nine service users) provided their comments on the design of our questionnaire which helped further refine the wordings and clarity of the questionnaire. Secondly, we will recruit persons with lived experience of mental illness to be the paid fieldworkers to collect data during the trial. They will undergo training in the university, will be shown how to work with the research participants (e.g., responding to commonly asked questions) and will receive ongoing support and coaching. Thirdly, the final results of the study will be disseminated to study participants and the wider public through public forum and seminar organised by the partnered agencies and the funder as well.

Outcome measures

The Recovery Assessment Scale (RAS)[37] will be used to evaluate the primary outcome, i.e., personal recovery in five areas, including personal confidence and hope, willingness to ask for help, goal and success orientation, reliance on others, and no domination by symptoms.[17,30] The items are rated on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree), with a higher score indicating greater perceived recovery. The scale has been used in an RCT of a peer-led program [38] and in a cross-cultural study [39]. It has also been translated into Chinese[38], yielding good internal consistency and concurrent and construct validity. Other secondary outcomes include validated scales on state of hope, level of symptoms, community integration,

mattering, working alliance, as well as goal achievements, functional outcomes and socio-demographic information will also be collected from service user participants. Additionally, working alliance and goal achievements of service users will be collected from case workers. The details of the measurements for measuring the primary and secondary outcomes are summarized in Table 2.

[INSERT Table 2]

Process evaluation

We will conduct a qualitative study parallel to the RCT to address the study objective about the therapeutic ingredients of SMCM and the link between fidelity features and clients' recovery outcomes. We will invite a total of 21 service users and nine case workers from the intervention group for in-depth interviews at the end of the 12-month assessment period (T_2). Therefore, seven service users and three case workers will be chosen from each of the three intervention sites using a maximum variation technique which is a form of purposive sampling.[40] The selection of extreme and typical participants will be based on the richness of strengths identified in the Strengths Assessment at T_2 and the manner of completion (e.g., using the service users' language and explaining the significance of the strength to the person). Service user participants who do not use the Strengths Assessment intensely will also be involved in the qualitative study. Semi-structured interview protocol will be developed and used during the interviews for exploring the perceived therapeutic ingredients, perceptions of the benefits, challenges of the intervention, and the suggestions for improvement among the service user and case worker participants. These interviews will be conducted at the ICCMWs for the sake of convenience.

Statistical analyses

We will examine the effects of the SMCM intervention on participants outcomes compared to the SMILE group. Background information, including socio-demographic characteristics and all outcome variables, will be summarized using means and standard deviations for continuous variables and frequencies, percentages, and cross-tabulations for categorical variables. Univariate and multivariate outliers, histograms, probability plots, and residual plots will be examined to select the best-fitting models. We will then conduct growth curve modeling[41] to test whether or

not there are any post-intervention significant improvements in participants' outcomes (i.e., RAS, Hope, Community Integration, symptoms levels). Clients will be nested within case workers who are nested within agencies (implementation sites). Given the small sample size at the worker and agency levels, a fixed-effects model will be used at the agency level to control for potential agency effects. We will perform intent-to-treat analysis to reflect the real-world setting. Model fit will be evaluated using the multi-index approach,[42] based on the root mean square error of approximation (RMSEA values < .08 are acceptable, but values < .05 are preferred) and comparative fit index (CFI values > .90 are acceptable, but values > .95 are preferred). Full information maximum likelihood will be used to estimate the model, which is also an appropriate method to handle missing data.[43]

Regarding the qualitative data, we will use grounded theory methodology to guide the analyses.[44, 45] The grounded theory provides a systematic framework around which interview data can be analysed and interpreted through the use of coding techniques and the constant comparative method. The entire interview process will be audio-recorded and transcribed subsequent analysis. Each interview will be coded into NVivo. The data will be subject to four layers of analysis.[46] The first layer of analysis will involve organizing the material by employing the General Inductive Method.[47] The researchers will read the transcriptions multiple times, develop a coding frame, and further read and discuss based on this frame. The second layer of analysis will involve conceptualizing key content into broad themes according to their relevance to the research objective pertaining to the relationships among the fidelity features of SMCM implementation, therapeutic ingredients, and client outcomes. The third layer will involve further discussion and reading; a limited number of key narratives will identify phases, pathways, processes, and mechanisms that operate in relation to SMCM implementation and intervention outcomes. The final layer will explore the extent of convergence and divergence between these different narratives. Convergent themes help identify the common pathways that are likely to be involved in explaining SMCM intervention outcomes. Divergent themes help identify alternatives that may or may not involve increases in positive responses to SMCM intervention. The research rigour of the results will be strengthened by the two following methods. First, the triangulation of data sources refers to carefully reading and comparing the fidelity assessment data and interview findings obtained from service users and case workers. Second, we will perform members checking by sending a summary of the findings to all the participants joining

the interviews for comments, and check whether the researchers' interpretations of the data match with the participants' perceptions of their experiences.

DISCUSSION

The search for effective interventions to promote recovery from mental illnesses and improve outcomes of the people with mental illnesses should be a priority for mental health care services. Although SMCM has been widely implemented in the Western context, its application and effectiveness in non-western contexts have not been well-studied. The current study aims to fill in the gaps.

Successful confirmation of the effectiveness of SMCM can have theoretical, clinical and societal contributions. First, the findings will generate new knowledge about SMCM that will significantly extend and refine the existing literature on strengths-based practice in mental health such as which section(s) of the Fidelity Scale may account for the service users' improved outcomes. Second, clinicians believe that they are already providing recovery-oriented care. Nevertheless, they do not have specific tools to guide their practices. So if proved to be effective, SMCM can provide robust, structured, evidence-based guidelines for strengths-based practices in Hong Kong and other countries. In addition, more service users with mental illnesses will benefit from the interventions. Lastly, by identifying service users' strengths and showing them how to achieve their aspirations, a strengths-based approach can help minimize the stigmatization of service users who are often perceived negatively by the rest of the population. This may in turn help people with mental illnesses integrate into the community and improve their subjective well-being.

Further studies should also consider a longer follow-up period to assess the sustainability of the intervention effects. Furthermore, more studies on the cost-effectiveness of SMCM can be carried out to provide new information pertaining to economic evaluations of SMCM to health policy makers.

ETHICS AND DISSEMINATION

The study received ethical approval from the Human Research Ethics Committee of The University of Hong Kong (EA1703078) and is currently recruiting participants. Written consent will be obtained from all participants and they will be provided with a detailed explanation of the

study objectives, the voluntary nature of their participation, their right to withdraw, and the risks and benefits of the study. The participants will be asked to sign two copies of the consent letter with one copy given to the participants and another one will be returned to the principal investigator of the present study for record purposes.

The current RCT and process evaluation will improve our understanding of the impacts of SMCM on service users' recovery, specifically, it will:

i. Demonstrate the benefits and unintended consequences of recovery-oriented, strengths-based services for individuals with mental illnesses;
ii. Highlight the key therapeutic ingredients of SMCM and how they affect SMCM outcomes; and
iii. Examine how best to implement SMCM in a Chinese community.

Our approach to knowledge translation will target at several key audiences. To disseminate our findings to service users and their families, the PI and the team will work with the local community and media. Healthcare professionals will benefit from the study's contribution to workforce training and professional meetings. We will disseminate our findings to researchers both locally and internationally through conference presentations and publications in peer-reviewed journals. Our results will also be disseminated through seminars organized by the PI's department and the websites of the participating NGOs.

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Author contributions ST and RG conceived the study. All authors contributed to the study design and are grant holders. ST and WY prepared the initial proposal for funding application, CN, SF and RG provided methodological expertise in the study design. All authors contributed to the refinement of the study protocol and approved the final manuscript.

Competing interests None.

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Data sharing statement: There are no data currently available.

Table 1. Key characteristics of SMCM intervention and SMILE control groups

Dimensions	SMILE Group	SMCM Group
1. Intervention Integrity & Infrastructure	- No routine fidelity review for the implementation of recovery-oriented services.	- To ensure a supportive strengths model context through the *Fidelity Scale*, which was designed to assess the adequacy of SMCM implementation in three core areas: structure, supervision/supervisor, and clinical/service.
2. Individual Sessions		
a. Strengths Assessments	- No specific tool for conducting initial assessments. - Unclear how it will focus on assessing people's strengths.	- To collect information on personal and environmental strengths using the *Strengths Assessment* tool as the basis of work. - Domains in daily living, assets, employment/education, supportive relations, wellness/health, leisure, spirituality/culture. - Ongoing process.
b. Recovery Plans	- Work on specific goals. - No specific tool.	- To create a mutual agenda for work, focusing on achieving the goals that the person has set. - To write down the person's goals (Passion Statement) and plan specific steps (short-term goals) to achieve the goals in the *Personal Recovery Plan*.
3. Group Supervision	- Adopt the existing supervision arrangements.	- To provide support and affirmation, ideas and learning. - Weekly supervision following specific steps: ✓ The presenting staff hand out clients' strengths assessments and specify the help needed from the group. ✓ The team are to clarify the assessment and brainstorm ideas. ✓ The presenting staff review the ideas and state the next steps.

Table 2. Measurements used for measuring primary and secondary outcomes

Outcome measure	Measurement	Details of the measurement	Completed by
Primary outcome			
Personal recovery	Recovery Assessment Scale (RAS)[37]	• Evaluates the primary outcome of personal recovery in five areas, including personal confidence and hope, willingness to ask for help, goal and success orientation, reliance on others, and no domination by symptoms[48,49]; • 24 items; 5-point Likert scale ranging from "strongly disagree" (1) to "strongly agree" (5), with a higher score indicating greater perceived recovery.	Service users
Secondary outcomes			
State of hope	State Hope Scale[50]	• Measures an individual's feelings of hope concerning ongoing events; • 6 items, 8-point Likert scale ranging from "definitely false" (1) to "definitely true" (8).	Service users
Mattering	Mattering Scale[51]	• Measures service user participants' perception of the degree to which they matter to their friends and family; • 3 items from the "Reliance" subscale; 5-point Likert scale ranging from "strongly disagree" (1) to "strongly agree" (5).	Service users
Community integration	Community Integration Measure (CIM)[52]	• Assesses the experience of community integration and participation and provides an understanding of adjustment to community after disability; • 10 items; 5-point Likert scale ranging from "strongly disagree" (1) to "strongly agree" (5).	Service users
Goal achievement	Created by research team	• A series of questions to gauge participants' goals and progress of goal achievement.	Service users & case

		• Service user participants will report goals in areas such as employment, housing, and study or leisure and rate how meaningful to them, ranging from "not meaningful at all" (1) to very meaning (5), and the progress of achieving these goals, ranging from "very unsatisfactory" (1) to "very satisfactory" (5).	workers
Psychiatric symptoms	Colorado Symptom Index[53,54]	• Measures the frequency of psychiatric symptoms experienced in the last month. • 14 items; 5-point Likert scale ranging from "not at all" (1) to "at least every day" (5).	Service users
Working alliance	Working Alliance Inventory (WAI) – client[55,56]	• Evaluates how well the relationship between the service user and case worker. • 12 items; 7-point Likert scale ranging from "never" (1) to "always" (7).	Service users
	Working Alliance Inventory (WAI) – therapist[55,57]	• Evaluates how well the relationship between the service user and case worker. • 12 items; 7-point Likert scale ranging from "never" (1) to "always" (7).	Case workers
Functional outcomes	Created by research team	• Information about service user participants' vocational outcomes, hospitalization, housing, and demographics.	Service users & Case workers

Figure 1. Salient concepts of Strengths Model Case Management (modified from Rapp & Goscha, 2011, p.50)[12]

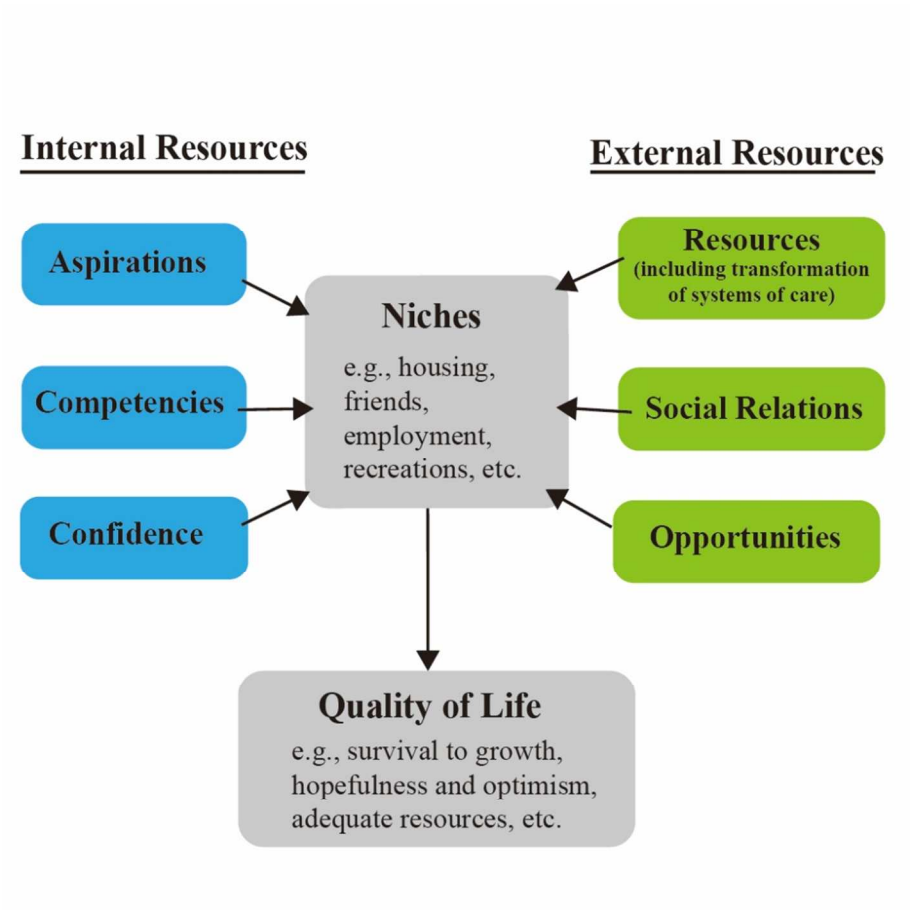
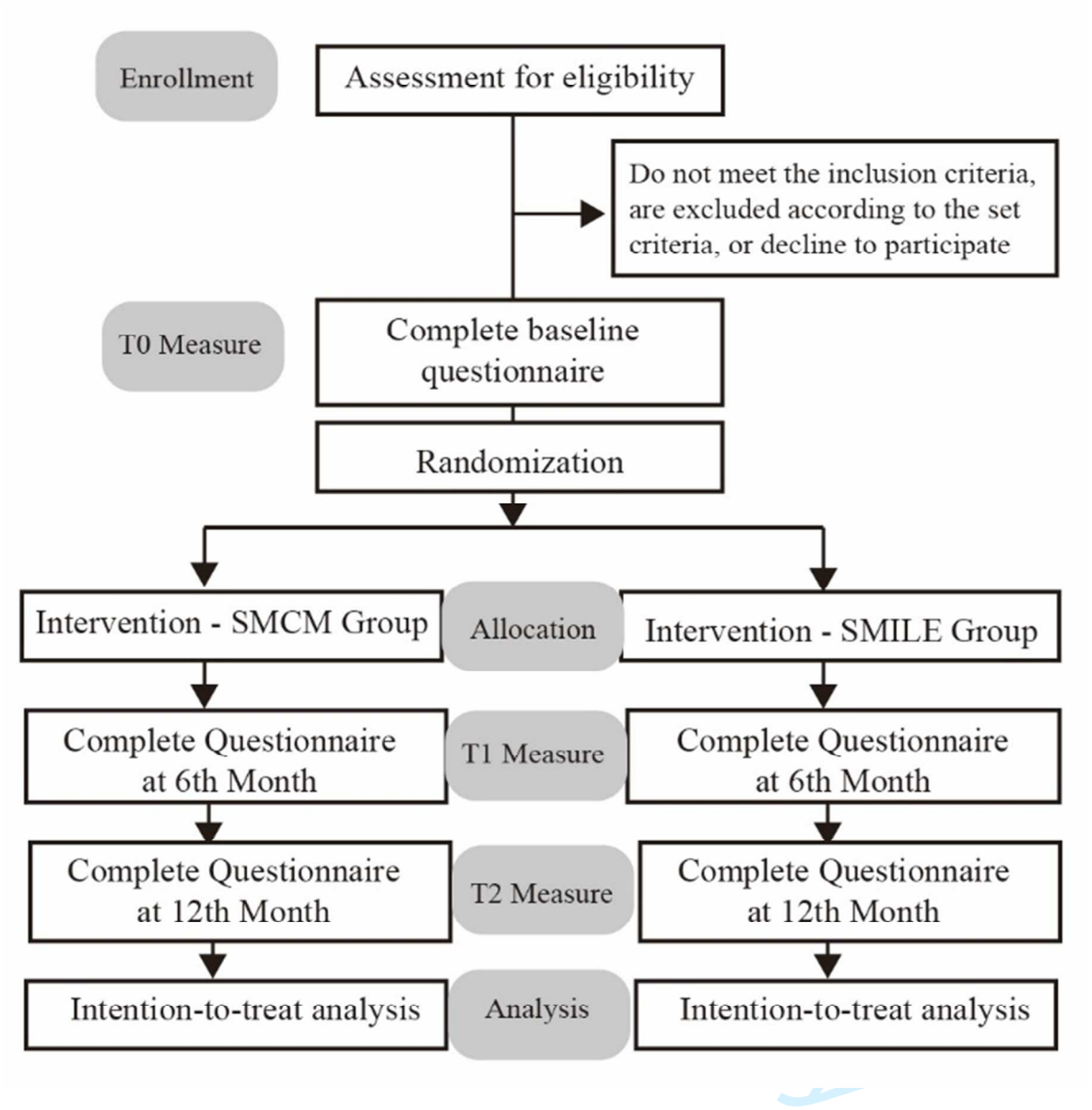


Figure 2. CONSORT diagram reflecting the flow of participants through the current study



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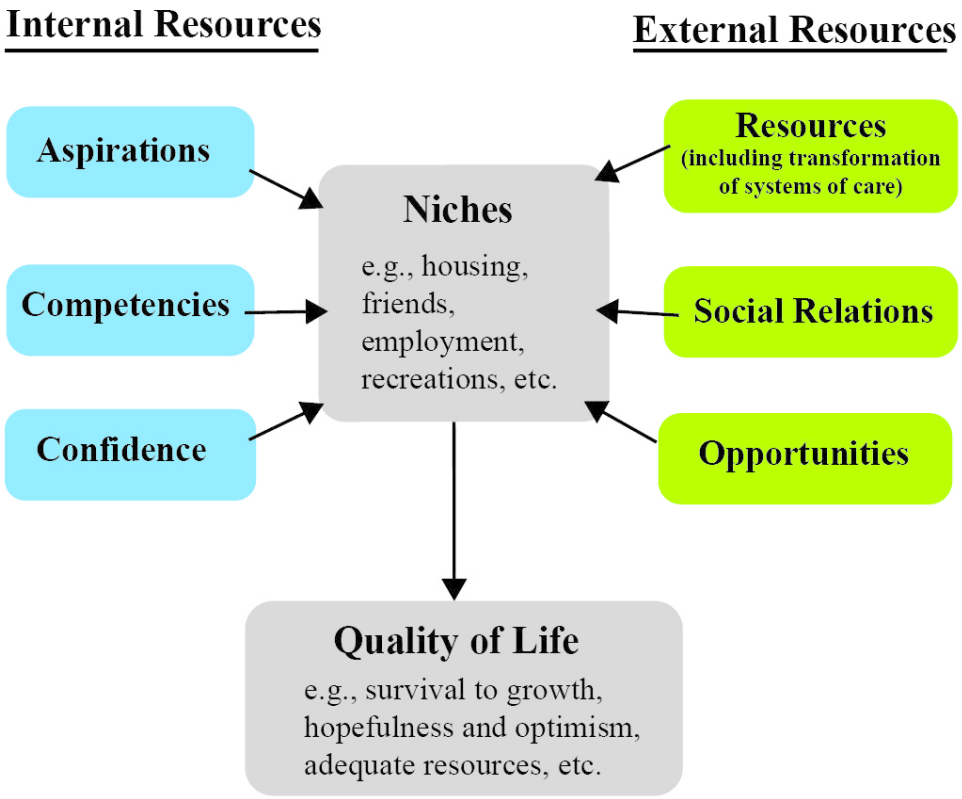

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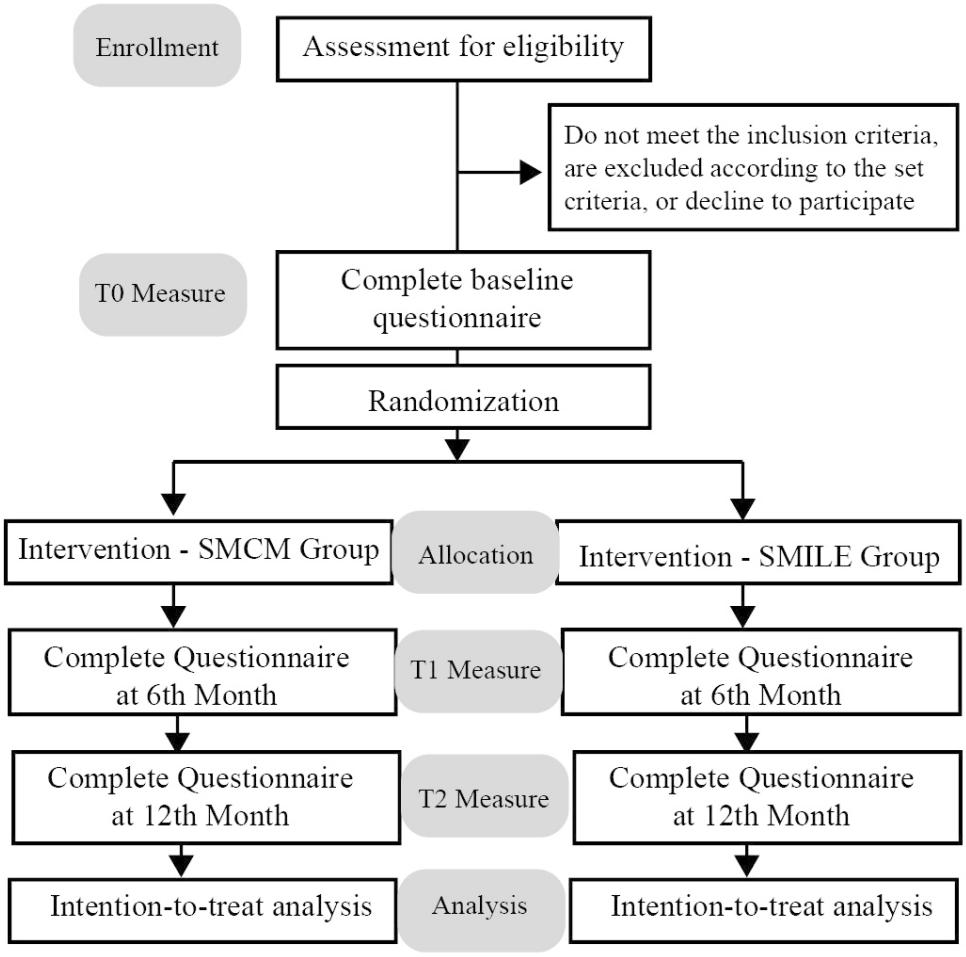

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SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Section/item	Item No	Description	Study protocol for a RCT evaluating effectiveness of SMCM in HK
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Yes [refer to the Title – Study design (RCT), population (Chinese mental health service users), intervention (SMCM)]
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Yes (Trial registration number)
	2b	All items from the World Health Organization Trial Registration Data Set	Yes (for the registration)
Protocol version	3	Date and version identifier	Yes
Funding	4	Sources and types of financial, material, and other support	Yes (refer to Funding section)
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Yes (below the title)
	5b	Name and contact information for the trial sponsor	Partially yes (no contact information)

	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	Yes (Funding Section)
	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)	There were description about roles of named investigators in the original funding proposal; no, we do not have a data management team per se however the data will be looked after carefully by the PI and the team.
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	Yes

	6b	Explanation for choice of comparators	Yes, mentioned briefly in the original funding proposal and the PI has conducted a critical review of the topic and it was published- Tse et al., Uses of strength-based interventions for people with serious mental illness: A critical review. *International Journal of Social Psychiatry, 62*(3), 281-291.
Objectives	7	Specific objectives or hypotheses	Yes (refer to Study Objectives)
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)	Yes
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	Yes
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)	Yes
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Yes
	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)	N.A.

	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Yes (To ensure the integrity of the intervention use in two arms and adherence of the SMCM model, two raters will monitor the intervention by using the Fidelity Scale.)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	No
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	Yes
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)	Yes, Figure 2 shows the flow of participants
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	Yes (Sample size and statistical power)

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	No strategies were stated explicitly however the research team has 7 years of experience of working with the partnered NGOs therefore we will meet regularly to monitor the progress, there are monetary incentive to reinforce participation.
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	Yes
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	Yes
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Yes
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Refer to randomization
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Refer to randomization

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	Yes
	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	No
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	There were detailed statement/ plan about data storage and security in the local ethics application (Institutional Review Board [IRB]). Although we did not have explicit plan about data quality management, we will be doing it (e.g., 10% checking, usual data cleaning procedures).
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	Yes
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA

	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)	Yes
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	Although we did not institutionalise the DMC, the research team will be doing it (e.g., data cleaning, checking the quality and completeness).
	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	As part of good practice and our prior experience in conducting trial, we will perform interim analysis although we did not have stopping guidelines.
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	Yes (following the research ethics)
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Yes (2 raters and Fidelity Scale)
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Yes

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)	We are required by the university ethics and IRB to report deviation from the protocol; there are specific steps and forms to adhere to.
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Yes (written consent)
	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	They are specified in the ethical application.
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Yes
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	Although we did not have an explicit statement, it will be handled by the PI.
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	Yes

	31b	Authorship eligibility guidelines and any intended use of professional writers	Although we did not have explicit statement about it, we will follow to the standard practice (the 4 conditions; https://www.bmj.com/about-bmj/resources-authors/article-submission/authorship-contributorship).
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	It was included in the original funding proposal section 10 "Release of completion report, data archive possibilities, and public access of publications resulting from research funded by the RGC" (Research Grant Council).
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Research consent form and information sheet were included in original ethical application; this study did not have authorised surrogates or proxy person to consent.

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.

BMJ Open

Study protocol for a randomised controlled trial evaluating the effectiveness of Strengths Model Case Management (SMCM) with Chinese mental health service users in Hong Kong

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Secondary Subject Heading:	Evidence based practice
Keywords:	MENTAL HEALTH, Clinical trials < THERAPEUTICS, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PSYCHIATRY, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

Study protocol for a randomised controlled trial evaluating the effectiveness of Strengths Model Case Management (SMCM) with Chinese mental health service users in Hong Kong

(revised version 19 March 2019)

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ABSTRACT

Introduction: Strengths-based approaches mobilize individual and environmental resources that can facilitate the recovery of people with mental illness. Strengths Model Case Management (SMCM), developed by Rapp and Goscha through collaborative efforts at the University of Kansas, offers a structured and innovative intervention. As evidence of the effectiveness of strengths-based interventions come from Western studies, which lacked rigorous research design or failed to assure fidelity to the model, we aim to fill these gaps and conduct a randomised controlled trial to test the effectiveness of SMCM for individuals with mental illness in Hong Kong.

Methods and analysis: This will be a randomised controlled trial of SMCM. Assuming a medium intervention effect (Cohen's d = .60) with 30% missing data (including dropouts), 210 service users aged 18 or above will be recruited from three community mental health centres. They will be randomly assigned to SMCM groups (intervention) or SMILE groups (control) in a 1:1 ratio. The SMCM groups will receive strengths model interventions from case workers, whereas, the SMILE groups will receive generic care from case workers with an attention placebo. The case workers will all be embedded in the community centres and will be required to provide a session with service users in both groups at least once every fortnight. There will be two groups of case workers for the intervention and control groups, respectively. The effectiveness of the SMCM will be compared between the two groups of service users with outcomes at baseline, six and 12 months after recruitment. Functional outcomes will also be reported by case workers. Data on working alliances and goal attainment will be collected from individual case workers. Qualitative evaluation will be conducted to identify the therapeutic ingredients and conditions leading to positive outcomes. Trained outcome assessors will be blind to the group allocation.

Ethics and dissemination: Ethical approval from the Human Research Ethics Committee at the University of Hong Kong has been obtained (HRECNCF: EA1703078). The results will be disseminated to service users and their families via the media, to healthcare professionals via professional training and meetings, and to researchers via conferences and publications.

Trial registration number:

Australian New Zealand Clinical Trials Registry (ACTRN) 12617001435370.

Article summary

Strengths and limitations of this study:

- First study using a randomised controlled trial and a rigorous mixed-methods design to assess the effectiveness of SMCM conducted in Hong Kong and worldwide. Fidelity or integrity of the SMCM intervention will be monitored to explore its effects on service users' outcomes.
- Evidence of implementing SMCM among Chinese in community mental health settings will be established and the key therapeutic ingredients of SMCM will be identified.
- This study provides a unique opportunity to examine how the SMCM should be adapted to ensure practice and services are culturally responsive (based on our best knowledge about SMCM, we have made preliminary cultural adaptations [e.g., translation of the assessment, explaining the concept of strength] before the trial).
- Case workers of SMCM and SMILE (control) groups in the same community mental health centre may share the same philosophy (e.g., recovery approach) and culture of the agency leading to potential contamination between the two groups.
- Service users may not stay in the community centre (due to withdrawing from the study or being discharged from the service) for the entire 12-month trial period.

Keywords: Mental Health, Clinical trials, Protocols & guidelines, Psychiatry, Organisation of health services

Word count: 4908

INTRODUCTION

Common mental disorders (CMD) such as depression and anxiety are very prevalent in the population globally. It is estimated that over 300 million people experience depression worldwide.[1] A population-based study, Hong Kong Mental Morbidity Survey 2010-2013, reported that 13.3% and 2.5% of adults aged 16-75 years were diagnosed with CMD[2] and psychotic disorders,[3] respectively. The consequences of CMD are reflected in the results of the 2010 Global Burden of Diseases, Injuries, and Risk Factors Study (GBD 2010),[4] which reported that bipolar disorder and schizophrenia accounted for 7.0% and 7.4% of disability adjusted life years (DALY), respectively. In addition, the global costs of mental illness were estimated at US$2.5 trillion in 2010 and this figure is set to more than double to US$6 trillion by 2030.[5] Mental illness not only affect the physical and psychological health of the individuals concerned, but also their families, caregivers, and friends. Therefore, better treatment and planning of care are essential to promote recovery from mental illness and improve outcomes.

Across the globe, traditional treatments for mental illness primarily consist of medication.[6] However, mental illness is often long lasting and recurrent, so, taking medication alone may not be sufficient to achieve personal recovery, which is broadly defined as "a deeply personal, unique process of changing one's attitudes, values, feelings, goals, skills and/or roles … a way of living a satisfying, hopeful and contributing life even with the limitations caused by illness".[7] It also refers to the process of individual psychological adaptation to an illness and addressing functional impairment.[8] With the proliferation of positive psychology advocated by Seligman,[9] more empirical studies focus on strengths of character, which are defined as "positive traits reflected in thoughts, feelings, and behaviors"[10] (p. 603) and positive experiences such as life satisfaction.[10] In recent years, more researchers have advocated strengths-based approaches, which mobilize individual and environmental resources that can facilitate recovery among people with mental illness.[11,12] Strengths model case management (SMCM) has gained increasing favour among practitioners since the 1980s in Kansas.[13,14]

Conceptual framework: Kansas model, Strengths Model Case Management (SMCM)

Strengths model case management (SMCM) was developed by Rapp and Goscha through collaborative efforts at the University of Kansas (KU).[12,13] The Kansas model of SMCM aims to enhance recovery through instilling hope and empowering the choices and autonomy of service

users, rather than focusing on deficits. Case management refers to the process of assessing needs, implementing a service plan, and monitoring progress to bring about positive outcomes.[15,16]

SMCM consists of four main core elements, including strengths assessment, personal recovery plan, group supervision, and field mentoring. The strengths assessment is used to appraise the service users' strengths, niches in the community, and other attributes such as hope, self-efficacy, and the resources available in the family and community, while the personal recovery plan uses the information obtained from the strengths assessment to derive a plan that consists of recovery goals that are meaningful to the service users. Co-construction of recovery goals between service users and case workers can be challenging[17] so the steps towards achieving a goal should be small, specific, and measurable. Group supervision aims to provide a supportive environment for case workers to help service users achieve the goals they identify. Furthermore, field mentoring will be provided to case workers on a regular basis or whenever necessary. It has been designed to help staff develop and refine their SMCM practice skills in the field with service users.

SMCM is guided by six major principles: (1) people with mental illness have the capacity to recover, reclaim, and transform their lives; (2) the focus is on the strengths of individuals; (3) the community is perceived as an oasis of resources; (4) the service user is the director of the helping process; (5) the worker-service user relationship is essential; and (6) the primary setting of the work is the community.[13] In addition, SMCM lays emphasis on three themes. First, case workers should be creative about how to help each service user achieve a life that brings purpose, meaning, and a valued identity. Second, SMCM does not neglect the problems and impediments that service users are facing. Instead, problems and obstacles are perceived within the context of the goals that the service user desires to achieve. Third, SMCM is not only about a change in clinical practice but also requires the transformation of our care systems such as policies and the way we communicate with each other to best support service users in finding niches within their community in which they can thrive. Figure 1 shows the important concepts of the SMCM framework.

[INSERT Figure 1]

Figure 1. Salient concepts of Strengths Model Case Management (modified from Rapp & Goscha, 2011, p.50)[13]

Most studies evaluating the effectiveness of SMCM in helping people with mental illness reported positive outcomes in many areas such as re-hospitalization, housing, employment, social support, family burden, and symptoms.[11,18-25] Similarly, in a recent review,[26] the results showed that the benefits associated with the strengths-based approach included reductions in the duration of stay in hospital, increases in service satisfaction, improvements in general attitudes towards recovery-relevant dimensions (e.g., self-efficacy and sense of hope), improvements in employment and educational outcomes, increases in the utilization of general services, and increases in job satisfaction as well as morale among mental health professionals. SMCM offers a promising alternative to traditional approaches focusing on service users' deficits.

Nevertheless, as the majority of studies about SMCM have been conducted in the Western context, its use and outcomes lack cultural sensitivity. Based on our best knowledge about SMCM, we have made preliminary cultural adaptations (e.g., translating the forms used in the Strengths Assessment and Personal Recovery Plan, using local terms and examples to explain the concept of strength) before the trial. The current study will provide the best opportunity to investigate SMCM's cultural (e.g., under the influence of Taoism, Chinese people tend to be more reserved in stating their strengths and successes) and structural (e.g., the caseload sizes, the ratio of supervisor to case worker, and so on) compatibility and to understand how SMCM can be best implemented in community mental health settings such as Integrated Community Centres for Mental Wellness. According to the Model[12], the structure of the service, including a low caseload size, a low supervisor to case worker ratio and the presence of structured supervision sessions, are vital to the implementation and effectiveness of SMCM. However, the structure of mental health services is different in Hong Kong compared to the US, for example, the caseload in mental health services remains high (the Hospital Authority in Hong Kong reported that in 2016, ratio of case worker to individual with severe mental illness residing in the community was around 1:47 on average), therefore it might be a factor affecting the results of SMCM. Only intervention teams that have achieved high fidelity scores will be included in the present trial (for details, see Method section).

Furthermore, reviews of the existing literature indicate that there are limitations to the existing studies. First, among 11 empirical studies[18,20-22,25,27-32] that have investigated the effectiveness of SMCM in mental healthcare settings, only a single study used a randomised controlled trial (RCT) design, which is considered to be the gold standard[33] in research, and other studies used either secondary data analyses, quasi-experimental with a pre- and post-design, or

between-group comparison. Second, the RCTs on so-called "strengths-based interventions" were all conducted prior to the year 2000. Furthermore, none of the studies used fidelity assessment to ensure that the intervention group was actually using the strengths model.[26] Thus the proposed study seeks to fill this gap in the existing body of literature. Next, results from recent studies showed that SMCM fidelity affects intervention outcomes across service sites, with high fidelity SMCM associated with lower rates of psychiatric hospitalization and higher employment rates.[32] However, little is known about the important constituent of the strengths model approach and how the fidelity scores (or distribution across different items) have impacted on service users' recovery outcome. Finally, the conceptualization of strengths is culturally defined through linguistics, metaphors, icons, and folklore traditions.[34] Chinese people view their strengths as ever-changing, universal, and dialectical in nature, as well as being shaped by their upbringing/family traditions and the lived experience of mental illness. Introspection is critical in the discovery of strengths, which could be influenced by the Taoist philosophy and the Confucius's The Doctrine of Mean (Zhongyong 中庸)[34,35]. Therefore, preliminary cultural adaptation of SMCM before implementing it in a Chinese (or, more broadly, Asian) context is of paramount importance.[35]

Study objectives

Building on the experience of conducting an earlier trial using a non-randomised design[36] in a residential setting, the primary objective of the present study is to assess the effectiveness of SMCM when implemented among service users in Integrated Community Centres for Mental Wellness (ICCMWs) in Hong Kong, using a randomised controlled trial (RCT) design. Specifically, we hypothesize that service users in the high-fidelity SMCM group will experience higher levels of personal recovery, as well as symptom reductions, improved hope, community integration, mattering, working alliances, and goal attainment, relative to their counterparts in a control group, which incorporates an attention placebo. The second objective is to evaluate the fidelity features of SMCM implementation and the major therapeutic ingredients that have an effect on service users' outcomes.

METHODS

Study design and setting

By choosing a mixed-methods design, we will use quantitative methods to evaluate the effectiveness of SMCM on multidimensional outcomes, whilst, a qualitative study will be used to

examine the fidelity features (e.g., structure and supervision) and therapeutic ingredients that may be related to the intervention outcomes. These two methods supplement each other. In terms of the settings, the study will take the form of an RCT to examine the effectiveness of SMCM for service users with mental illness. It will consist of two arms: an SMCM intervention group and a control group (called "SMILE" group — not an acronym). The service users in both arms will be recruited from the ICCMWs of three non-governmental organizations. To achieve diversity in the study samples, the NGOs joining the present study are located in different districts in Hong Kong. Service users attending ICCMWs are individuals with either suspected mental health problems or diagnosed mental illnesses.

Sample size and statistical power

We performed Monte Carlo simulations to estimate the required sample size by using the methods recommended by Muthén and Muthén.[37] We assumed a medium effect size (Cohen's d = .6) for the slope (change rate) difference of the primary outcome measure (a mean slope difference between the intervention and control groups) based on previous empirical studies. We assumed 15% and 30% missing data at 6 months and 12 months, respectively.[26] A total of 210 service users (n = 105 per group) will be required for a statistical power of .80 to detect a medium effect with the amount of missing data taken into consideration. We adopted the fixed-effects model in accounting for the cluster effects given the small cluster size (e.g., three centres).

Participants

We will recruit a total of 210 service users from three ICCMWs. Upon the arrival of the service users, a trained social worker will undertake the recruitment. He/she will be responsible for screening the eligibility of service users based on the inclusion and exclusion criteria. The inclusion criteria include:

(i) being a service user of mental health services in ICCMWs;
(ii) being aged 18 or above;
(iii) being Chinese; the ability to read Chinese and speak Cantonese;
(iv) being diagnosed with mental illness, including major depressive disorder, anxiety disorder, bipolar disorder, and psychotic disorders, by a psychiatrist; and
(v) the ability to provide written informed consent to join the study and a willingness to be allocated to either group (SMCM or SMILE).

The exclusion criteria will be applied to those service users who are:

(i) likely to engage in immediate risk behaviour, such as suicide and/or violence; and/or

(ii) affected by overt psychotic symptoms and unable to sustain a meaningful conversation for more than 10 minutes as identified by case workers.

Incentives in the form of supermarket coupons (worth HK$50) will be given to the service users at all three time points, as compensation for participating in the study.

Recruitment of Case workers

The case workers responsible for the delivery of SMCM intervention are ICCMWs staff (e.g., registered social worker, program worker, occupational therapist, nurse). They must have received prior training on SMCM provided by KU and agree to participate in ongoing group supervision (see *Intervention groups* subsection). There is a standard, two-day training on SMCM covering nine aspects of the practices such as day one on "Recovery – Illuminating the Path of Hope", "Strengths Assessment – Amplifying Wellness", and day two on "Relationship/Engagement – Partners in Recovery", and "Resource Acquisition – Community Mental Health". The programme details are included as supplementary information.

Randomisation

After screening for their eligibility, all service users will be asked to complete a face-to-face baseline questionnaire (T_0). The social worker will contact the research team to obtain group allocation information and participants will be randomly allocated to either the SMCM or SMILE group in a 1:1 ratio, according to a pre-determined randomisation list generated by an online randomisation program (www.randomization.com). Block randomisation will be performed to reduce bias and achieve balance in allocating participants into the intervention and control groups. Rolling enrolment will be used.

Participants with the group assignment will then be followed up by case workers using the SMCM or SMILE protocol and will be asked to complete the same questionnaires at 6 months (T_1) and 12 months (T_2). All case workers are required to conduct a session with service users in both intervention and control groups at least once every fortnight. Service user participants will be informed that there are two forms of psychosocial intervention, but they do not know which

intervention they are allocated to. They can withdraw from the study at any time. The case workers in either the intervention or control group will not be blind to the group allocation as they will be the ones who provide the services to the users, but the trained outcome assessors who are peer researchers, will be blind to such information. In order to minimize contamination, case workers in the SMILE group will not be provided with any of the tools related to SMCM (e.g., Strengths Assessment, Personal Recovery Plan) or receive any strengths-based supervision. Figure 2 shows the CONSORT diagram, which illustrates the flow of participants throughout the research process.

[INSERT Figure 2]

Figure 2. CONSORT diagram reflecting the flow of participants through the current study

Intervention groups: SMCM group

The service user participants allocated to the SMCM group will receive individual sessions of about 30 minutes every fortnight. The SMCM intervention can only be delivered by case workers who have previously received training provided by KU. Case workers and supervisors will attend ongoing monthly group supervision led by Goscha (SMCM's author) via Skype. The Strengths Assessment and Personal Recovery Plan developed by the KU team will be used to guide the intervention sessions. During the intervention, the case workers will help the service users identify recovery goals that are meaningful to them and workers will attend weekly strengths-based supervision run at the ICCMWs. The Fidelity Scale of the service unit will be used every 6 months to monitor if these high-fidelity activities take place as expected. A leadership team consisting of a unit-in-charge and a SMCM supervisor will be established in each ICCMW to oversee the activities.

Control groups: SMILE group

Service users in the SMILE control group will receive a generic intervention (i.e., treatment as usual) which will include recovery groups, medical appointments, leisure/hobby groups, and general community activities. Case workers will have fortnightly contact with service users, which will serve as the attention placebo. Case workers in the control group will call service users on the phone or will meet with them in person for some groups and centre activities. Table 1 summarizes the key characteristics of the SMCM intervention and SMILE control groups.

[INSERT Table 1]

To ensure the integrity of the intervention used in the SMCM and SMILE groups, as well as the adherence to the model, two raters with a thorough understanding of SMCM will closely monitor the intervention by using the Fidelity Scale at 1 (baseline), 6, and 12 months after the intervention starts. The Fidelity Scale was developed to ensure that all components adhered to the model when SMCM was implemented. The scale is composed of nine items across three areas: structure, supervision/supervisor, and clinical/service. In order to qualify to participate in the present study, SMCM teams will need to achieve an overall fidelity score of 36 (out of 45) on the Fidelity Scale including an average rating of four out of five in each of the three core areas. The fidelity data will be collected through interviews with staff and service users, site observations, and reviews of the SMCM tools and charts. The fidelity scores can be improved by three main methods: 1) providing the team with specific comments about which item(s) are under-scored (i.e., scores below 4); 2) having deeper discussions with the team about the difficulties they are facing; and 3) learning from group supervision and field mentoring.

Patient and Public Involvement

Given the increasing importance of the role played by patients and public involvement in research and the study objectives, which aim to examine the effectiveness of SMCM, we involved the service users when we conducted a pilot study in September 2017. Three service users from each ICCMW (i.e., a total of nine service users) provided their comments on the design of our questionnaire, which helped further refine the wording and clarity of the questionnaire. Secondly, we will recruit people with lived experience of mental illness as the paid fieldworkers to collect data during the trial. They will undergo training in the university, will be shown how to work with the research participants (e.g., responding to commonly asked questions), and will receive ongoing support and coaching. Thirdly, the final results of the study will be disseminated to study participants and the wider public through public fora and seminars organised by the partnered agencies and the funder.

Outcome measures

The Recovery Assessment Scale (RAS)[38] will be used to evaluate the primary outcomes, that is to say, personal recovery in five areas, including personal confidence and hope, willingness to ask for help, goal and success orientation, reliance on others, and no domination by symptoms.[18,31]

The items will be rated on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree), with a higher score indicating greater perceived recovery. The scale has been used in an RCT of a peer-led program[39] and in a cross-cultural study.[1] RAS has the benefit that it has already gone through the cross-cultural adaptation process; it has been translated into Chinese,[39] yielding good internal consistency and concurrent and construct validity. Other secondary outcomes include validated scales on state of hope, level of symptoms, community integration, mattering, working alliance, as well as goal achievements, functional outcomes, and socio-demographic information will also be collected from service user participants. Additionally, working alliance and goal achievements of service users will be collected from case workers. The details of the measurements for measuring the primary and secondary outcomes are summarized in Table 2.

[INSERT Table 2]

Process evaluation

We will conduct a qualitative study parallel to the RCT to address the study objectives concerning the therapeutic ingredients of SMCM and the link between fidelity features and service users' recovery outcomes. The therapeutic ingredients of SMCM that will be identified are individual, such as state of hope, and environmental (such as community integration) strengths and resources, which help people with mental illness live a meaningful life and integrate into society. We will invite a total of 21 service users and nine case workers from the intervention group and control group respectively for individual interviews at the end of the 12-month assessment period (T_2). Therefore, seven service users and three case workers will be chosen from each of the three intervention and control sites using a maximum variation technique, which is a form of purposive sampling.[40] The selection of extreme and typical participants will be based on the richness of strengths identified in the Strengths Assessment at T_2 and the manner of completion (e.g., using the service users' language and explaining the significance of the strengths to the person). Service user participants who do not use the Strengths Assessment intensely will also be involved in the qualitative study. A semi-structured interview protocol will be developed and used during the interviews to explore the perceived therapeutic ingredients, perceptions of the benefits, challenges in the care and support taking place in either intervention or control group, and suggestions for improvement among the service user and case worker participants. These interviews will be conducted at the ICCMWs for the sake of convenience.

Statistical analyses

The quantitative data collected will be entered by the research assistants and at least 10% of the data will be checked. The data cleaning process, including checking the range and missing items, will be performed by research assistants under the supervision of the research team. We will examine the effects of the SMCM intervention on participant outcomes compared to the SMILE group. Background information, including socio-demographic characteristics and all outcome variables, will be summarized using means and standard deviations for continuous variables and frequencies, percentages, and cross-tabulations for categorical variables. Univariate and multivariate outliers, histograms, probability plots, and residual plots will be examined to select the best-fitting models. We will then conduct growth curve modeling[41] to test whether or not there are any post-intervention significant improvements in participants' outcomes (i.e., RAS, Hope, Community Integration, symptoms levels) across three time points at baseline, six months, and 12 months. Service users will be nested within case workers who are nested within agencies (implementation sites). Given the small sample size at the worker and agency levels, a fixed-effects model will be used at the agency level to control for potential agency effects. Model fit will be evaluated using the multi-index approach,[42] based on the root mean square error of approximation (RMSEA values < .08 are acceptable, but values < .05 are preferred) and comparative fit index (CFI values > .90 are acceptable, but values > .95 are preferred). Full information maximum likelihood will be used to estimate the model, which is also an appropriate method for handling missing data.[43]

Regarding the qualitative data, we will use grounded theory methodology to guide the analysis.[44, 45] Grounded theory provides a systematic framework around which interview data can be analysed and interpreted through the use of coding techniques and the constant comparative method. The entire interview process will be audio-recorded and transcribed, subsequent to analysis. Quality checks of the transcripts will be performed by a research assistant, who will compare recordings to transcripts for any missing or unclear words. Each interview will be coded in NVivo. The data will be subject to four layers of analysis.[46] The first layer of analysis will involve organizing the material by employing the General Inductive Method.[47] The researchers will read the transcripts multiple times, develop a coding framework, and further read and discuss based on this framework. The second layer of analysis will involve conceptualizing key content into broad themes according to their relevance to the research objective, pertaining to the

relationships among the fidelity features of SMCM implementation, therapeutic ingredients, and intervention outcomes. The third layer will involve further discussion and reading; a limited number of key narratives will identify phases, pathways, processes, and mechanisms that operate in relation to SMCM implementation and intervention outcomes. The final layer will explore the extent of convergence and divergence between these different narratives. Convergent themes help identify the common pathways that are likely to be involved in explaining SMCM intervention outcomes. Divergent themes help identify alternatives that may or may not involve increases in positive responses to SMCM intervention. The research rigour of the results will be strengthened by the following two methods. First, the triangulation of data sources refers to carefully reading and comparing the fidelity assessment data and interview findings obtained from service users and case workers. Second, we will perform member checking by sending a summary of the findings to all the participants joining the interviews for comments and check whether the researchers' interpretations of the data match the participants' perceptions of their experiences.

DISCUSSION

The search for effective interventions to promote recovery from mental illness and improve outcomes for service users should be a priority for mental health services. Although SMCM has been widely implemented in the Western context, its application and effectiveness in non-western contexts have not been well-studied. The current study aims to fill in the gaps.

Successful confirmation of the effectiveness of SMCM can have theoretical, clinical, and societal contributions. First, the findings will generate new knowledge about SMCM that will significantly extend and refine the existing literature on strengths-based practice in mental health such as which section(s) of the Fidelity Scale may account for the service users' improved outcomes. Second, mental health workers often believe that they are already providing recovery-oriented care. Nevertheless, they do not have specific tools to guide their practices. So if proved to be effective, SMCM can provide robust, structured, evidence-based guidelines for strengths-based practices in Hong Kong and other countries. In addition, more service users with mental illness will benefit from the interventions. Lastly, by identifying service users' strengths and showing them how to achieve their aspirations, a strengths-based approach can help minimize the stigmatization of service users who are often negatively perceived by the rest of the population. This may in turn help people with mental illness integrate into the community and improve their subjective well-being.

Further studies should also consider a longer follow-up period to assess the sustainability of the intervention effects. Furthermore, more studies on the cost-effectiveness of SMCM could be carried out to provide new information pertaining to economic evaluations of SMCM for health policy makers.

ETHICS AND DISSEMINATION

The study received ethical approval from the Human Research Ethics Committee of The University of Hong Kong (EA1703078) and is currently recruiting participants. Written consent will be obtained from all participants and they will be provided with a detailed explanation of the study objectives, the voluntary nature of their participation, their right to withdraw, and the risks and benefits of the study. The SMCM is an intervention which should not cause any physical or psychological harm to the participants. However, in case of any unanticipated problem arising or if the participant experiences any discomfort or distress when filling out the questionnaire, or answering the questions in the interview, the field worker should report this to the data-collection supervisor (IL and ST). The researchers (ST and WY) will help the participants to seek additional support from professionals. Also, the participants may choose not to answer the questions or to terminate the interview. The participants will be asked to sign two copies of the consent letter, with one copy given to the participants and the other one returned to the principal investigator of the present study for record keeping purposes. The consent forms will be kept separately from the data. All data collected, without personal identifiers, will be stored in the Principal Investigator's (PI) locked filing cabinet, whereas all digital or electronic recordings will be password protected and kept in the PI's computer for 5 years. Only the PI (ST) and the local Co-Investigators (CN, WY) of this research project will have access to the original trial dataset and solely for research purposes.

The current RCT and process evaluation will improve our understanding of the impact of SMCM on service users' recovery, specifically, it will:

i. Demonstrate the benefits and unintended consequences of recovery-oriented, strengths-based services for individuals with mental illness;
ii. Highlight the key therapeutic ingredients of SMCM and how they affect SMCM outcomes; and
iii. Examine how best to implement SMCM in a Chinese community.

Our approach to knowledge translation will target several key audiences. To disseminate our findings to service users and their families, the PI and the team will work with the local community and media. Healthcare professionals will benefit from the study's contribution to workforce training and professional meetings. We will disseminate our findings to researchers both locally and internationally through conference presentations and publications in peer-reviewed journals. Our results will also be disseminated through seminars organized by the PI's department and the websites of the participating NGOs.

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Author contributions ST and RG conceived the study. ST, CN, WY, RG and SF contributed to the study design and they are the research grant holders (named investigators). ST and WY prepared the initial proposal for funding application, CN, RG, and SF provided methodological expertise in the study design. ST, CN, WY and IL prepared the first draft of this study protocol. ST, CN, WY, RG, SF and IL contributed to the rewriting and refinements; all of the authors approved the final manuscript.

Competing interests None.

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Data sharing statement: There are no data currently available.

Table 1. Key characteristics of SMCM intervention and SMILE control groups

Dimensions	SMILE Group	SMCM Group
1. Intervention Integrity & Infrastructure	- No routine fidelity review for the implementation of recovery-oriented services.	- To ensure a supportive strengths model context through the *Fidelity Scale*, which was designed to assess the adequacy of SMCM implementation in three core areas: structure, supervision/supervisor, and clinical/service.
2. Individual Sessions		
a. Strengths Assessments	- There is no specific tool for assessing personal strengths, therefore they would not be assessed by the case worker in a structured way.	- To collect information on personal and environmental strengths using the *Strengths Assessment* tool as the basis of work. - Domains in daily living, assets, employment/education, supportive relations, wellness/health, leisure, spirituality/culture. - Ongoing process.
b. Recovery Plans	- Work on specific goals. - No specific tool.	- To create a mutual agenda for work, focusing on achieving the goals that the person has set. - To write down the person's goals (Passion Statement) and plan specific steps (short-term goals) to achieve the goals in the *Personal Recovery Plan*.
3. Group Supervision	- Adopt the existing supervision arrangements.	- To provide support and affirmation, ideas and learning. - Weekly supervision following specific steps: ✓ The presenting staff hand out service users' strengths assessments and specify the help needed from the group. ✓ The team are to clarify the assessment and brainstorm ideas. ✓ The presenting staff review the ideas and state the next steps.

Table 2. Measurements used for measuring primary and secondary outcomes

Outcome measure	Measurement	Details of the measurement	Completed by
Primary outcome			
Personal recovery	Recovery Assessment Scale (RAS)[38]	• Evaluates the primary outcome of personal recovery in five areas, including personal confidence and hope, willingness to ask for help, goal and success orientation, reliance on others, and no domination by symptoms[48,49]; • 24 items; 5-point Likert scale ranging from "strongly disagree" (1) to "strongly agree" (5), with a higher score indicating greater perceived recovery.	Service users
Secondary outcomes			
State of hope	State Hope Scale[50]	• Measures an individual's feelings of hope concerning ongoing events; • 6 items, 8-point Likert scale ranging from "definitely false" (1) to "definitely true" (8).	Service users
Mattering	Mattering Scale[51]	• Measures service user participants' perception of the degree to which they matter to their friends and family; • 3 items from the "Reliance" subscale; 5-point Likert scale ranging from "strongly disagree" (1) to "strongly agree" (5).	Service users
Community integration	Community Integration Measure (CIM)[52]	• Assesses the experience of community integration and participation and provides an understanding of adjustment to community after disability; • 10 items; 5-point Likert scale ranging from "strongly disagree" (1) to "strongly agree" (5).	Service users
Goal achievement	Created by research team	• A series of questions to gauge participants' goals and progress of goal achievement. • Service user participants will report goals in areas such as employment, housing, and study or	Service users & case workers

		leisure and rate how meaningful to them, ranging from "not meaningful at all" (1) to very meaning (5), and the progress of achieving these goals, ranging from "very unsatisfactory" (1) to "very satisfactory" (5).	
Psychiatric symptoms	Colorado Symptom Index[53,54]	• Measures the frequency of psychiatric symptoms experienced in the last month. • 14 items; 5-point Likert scale ranging from "not at all" (1) to "at least every day" (5).	Service users
Working alliance	Working Alliance Inventory (WAI) – client[55,56]	• Evaluates how well the relationship between the service user and case worker. • 12 items; 7-point Likert scale ranging from "never" (1) to "always" (7).	Service users
	Working Alliance Inventory (WAI) – therapist[55,57]	• Evaluates how well the relationship between the service user and case worker. • 12 items; 7-point Likert scale ranging from "never" (1) to "always" (7).	Case workers
Functional outcomes	Created by research team	• Information about service user participants' vocational outcomes, hospitalization, housing, and demographics.	Service users & Case workers

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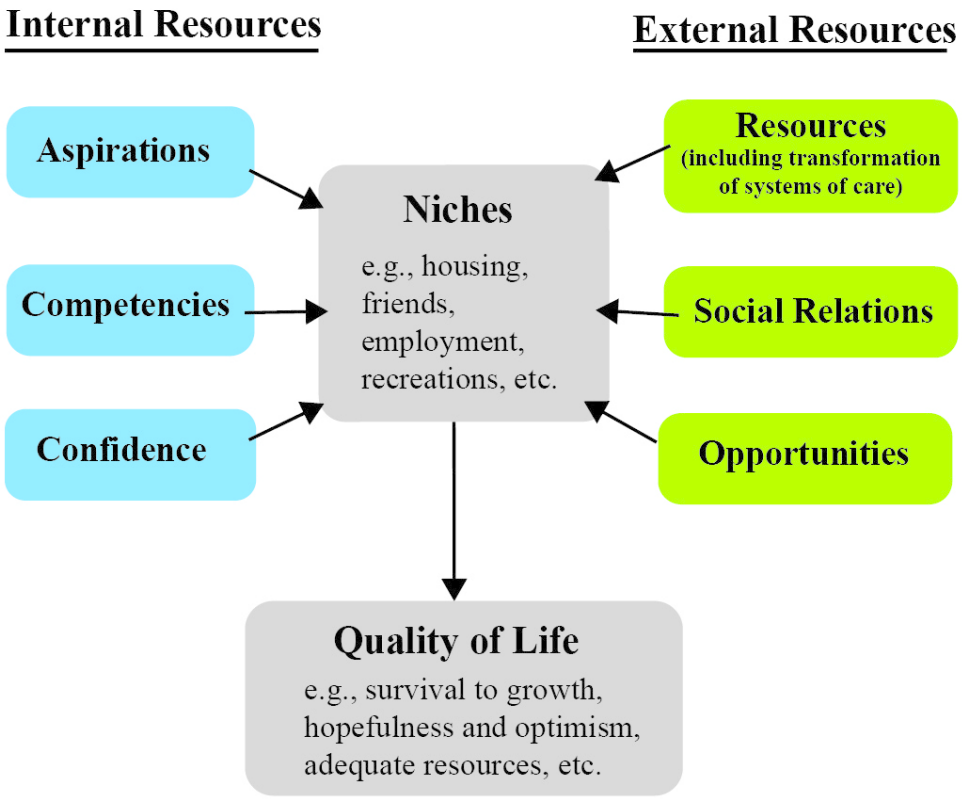

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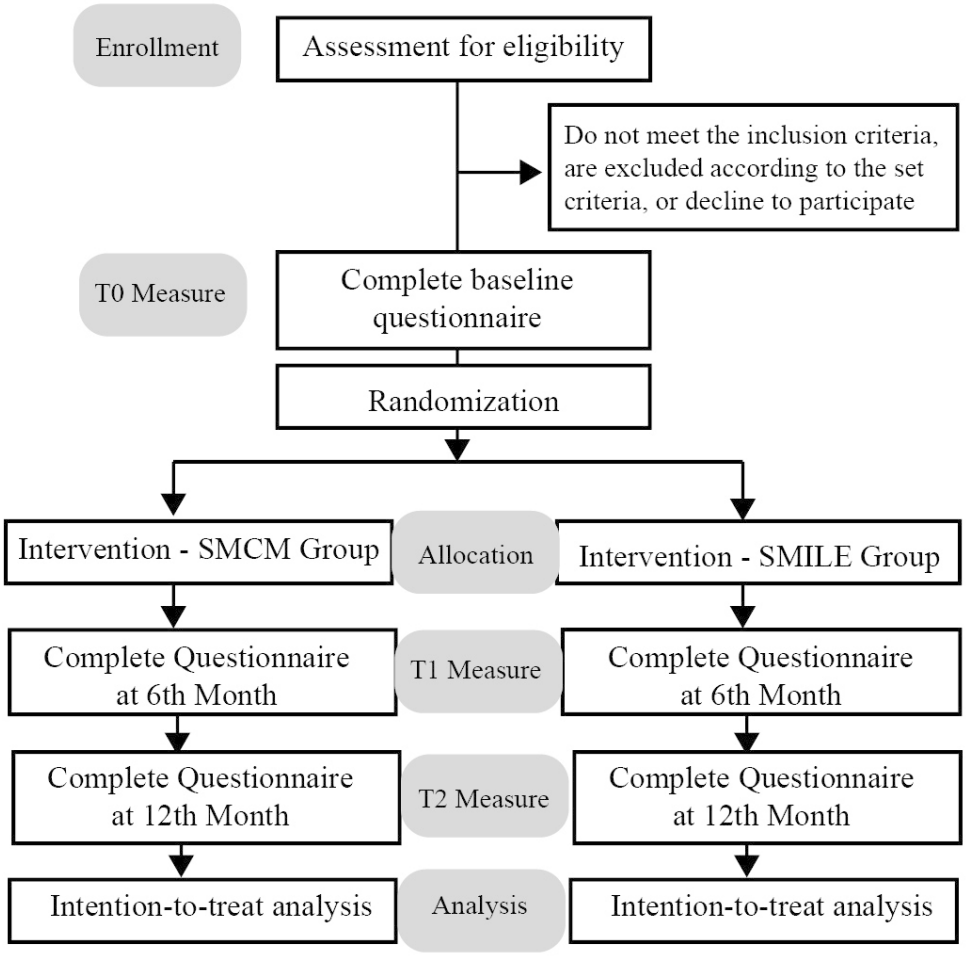

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Strengths Model Training 2-Day Workshop

Training for Frontline Workers

Teaching Format: Lectures, experiential learning activities (e.g., role play, reflective exercise) and case discussion

Target Participants: Social workers, nurses and other helping professionals supported by the service unit to implement Strengths Model Case Management (SMCM) and conduct strengths-based supervision.

Course description: This course aims to enhance frontline workers' understanding of the recovery model and contradicts the recovery model with the traditional deficits model. It examines in depth the philosophy behind strengths-based perspectives, and the research basis for this evidence-based, fidelity-monitored case management model – Strengths Model Case Management[1] . Furthermore, the concepts of strengths in mental health and how to effectively assess strengths in clients are also explored, with demonstrations from experienced workers. In addition, the importance of recovery goals and community in the strengths paradigm will also be discussed.

Intended learning outcomes; upon satisfactory completion of the workshop, participants will be able to:

1. Gain a critical understanding of the recovery paradigm and its significance in mental health;
2. Engage their clients more creatively and effectively in strengths-based interventions;
3. Conduct the strengths-based assessment;
4. Raise their awareness about ways in which community resources can be acquired or mobilized for clients.

Day One

Unit One: Introduction: Recovery – Illuminating the Path of Hope

Topics
Introduction
Overview of case management models; recovery model and the philosophy behind
What recovery is vs. what it is **not**
In-class exercise & reflection

Unit Two: Relationship/Engagement – Partners in Recovery

Topics
Relationship & engagement with your clients: The importance of partnership
Engaging your clients creatively: demonstration
In-class exercises & reflection
Strengths Assessment: An introduction

[1] Rapp, C. A., & Goscha, R. (2012). *The strengths model: A recovery-oriented approach to mental health services*. New York, NY: Oxford University Press.

Day Two

Unit Three: Strengths Assessment – Amplifying Wellness

Topics
Practical skills in implementing strengths assessment
Frequently asked questions from practitioners
Demonstration
Anchors and niches: The two critical concepts; their relations to strengths

Unit Four: Resource Acquisition – Community Mental Health

Topics
Motivational interviewing
Naturally occurring resources: Why it matters in the strengths model
Exercises: Identifying naturally occurring resources
Group supervision demo, Q&A

Readings

Elsie Jones-Smith. (2013). *Strengths-based therapy: Connecting theory, practice and skills.* Thousand Oaks, CA: SAGE.

Francis, Abraham P., Pulla, Venkat, Clark, Michael, Mariscal, E. Susana, and Ponnuswami, Ilango (2014). *Advancing social work in mental health through strengths-based practice.* Brisbane, QLD, Australia: Primrose Hall.

Francis, A. (2014). Strengths-based assessments and recovery in mental health: reflections from practice. *International Journal of Social Work and Human Services Practice*, 2, 264-271.

Hohman, M. (2011). *Motivational interviewing in social work practice.* New York, NY: Guilford Press.

Rapp, C. A., & Goscha, R. (2012). *The strengths model: A recovery-oriented approach to mental health services*. New York, NY: Oxford University Press.

Saleebey, D. (2012). *The strengths perspective in social work practice (4th edition)*. Boston, MA: Allyn & Bacon.

Stanard, R. P. (1999). The Effect of Training in a Strengths Model of Case Management on Client Outcomes in a Community Mental Health Center. *Community Mental Health Journal*, 35 (2), 169-179.

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SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Section/item	Item No	Description	Study protocol for a RCT evaluating effectiveness of SMCM in HK
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Yes [refer to the Title – Study design (RCT), population (Chinese mental health service users), intervention (SMCM)]
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Yes (Trial registration number)
	2b	All items from the World Health Organization Trial Registration Data Set	Yes (for the registration)
Protocol version	3	Date and version identifier	Yes
Funding	4	Sources and types of financial, material, and other support	Yes (refer to Funding section)
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Yes (below the title)
	5b	Name and contact information for the trial sponsor	Partially yes (no contact information)
	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	Yes (Funding Section)

	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)	There were description about roles of named investigators in the original funding proposal; no, we do not have a data management team per se however the data will be looked after carefully by the PI and the team.
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	Yes
	6b	Explanation for choice of comparators	Yes, mentioned briefly in the original funding proposal and the PI has conducted a critical review of the topic and it was published- Tse et al., Uses of strength-based interventions for people with serious mental illness: A critical review. *International Journal of Social Psychiatry, 62*(3), 281-291.
Objectives	7	Specific objectives or hypotheses	Yes (refer to Study Objectives)
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)	Yes
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	Yes

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)	Yes
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Yes
	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)	N.A.
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Yes (To ensure the integrity of the intervention use in two arms and adherence of the SMCM model, two raters will monitor the intervention by using the Fidelity Scale.)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	No
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	Yes
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)	Yes, Figure 2 shows the flow of participants
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	Yes (Sample size and statistical power)

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	No strategies were stated explicitly however the research team has 7 years of experience of working with the partnered NGOs therefore we will meet regularly to monitor the progress, there are monetary incentive to reinforce participation.
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	Yes
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	Yes
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Yes
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Refer to randomization
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Refer to randomization
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	Yes
	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	1. A supermarket coupon will be given to participants when they complete each set of questionnaire. 2. To appreciate the contribution of the research, a "Certificate of Appreciation" will be given to the participants after they have completed the T_2 questionnaire. 3. As this is a RCT of a strengths-model case management, a strengths-based planner will be distributed to the participants when they complete the T_2 questionnaire. 4. A brief summary of research progress will be given to the participants. For those who discontinue from the intervention, the worker will document the reasons for dropping out. Their data from the questionnaires completed previously, their number of sessions completed will be used for analysis.

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	There were detailed statement/ plan about data storage and security in the local ethics application (Institutional Review Board [IRB]). Although we did not have explicit plan about data quality management, we will be doing it (e.g., 10% checking, usual data cleaning procedures).
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	Yes
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	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)	Yes
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	Although we did not institutionalise the DMC, the project coordinator (IL) of this research project reports the data collection progress to the research team weekly. The data will be entered by the research assistants and the quality of data will be monitored by the researcher (WY). The research team holds regular research meetings once a month.
	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	As part of good practice and our prior experience in conducting trial, we will perform interim analysis although we did not have stopping guidelines.

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	Yes (following the research ethics)
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Yes (2 raters and Fidelity Scale)
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Yes
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)	We are required by the university ethics and IRB to report deviation from the protocol; there are specific steps and forms to adhere to.
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Yes (written consent)
	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	They are specified in the ethical application.
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Yes
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	Only PI (ST) and local Co-I (CN, WY) will have access to the final trial dataset and solely for research purposes. All identifiers will be removed.
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	Yes
	31b	Authorship eligibility guidelines and any intended use of professional writers	Although we did not have explicit statement about it, we will follow to the standard practice (the 4 conditions; https://www.bmj.com/about-bmj/resources-authors/article-submission/authorship-contributorship).
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	It was included in the original funding proposal section 10 “Release of completion report, data archive possibilities, and public access of publications resulting from research funded by the RGC” (Research Grant Council).
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Research consent form and information sheet were included in original ethical application; this study did not have authorised surrogates or proxy person to consent.
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