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[Intervention Protocol]

Motivational interviewing for improving functional and psychosocial outcomes among stroke survivors

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To evaluate the benefits and harms of motivational interviewing for functional and psychosocial outcomes in stroke survivors, compared to no intervention, waiting list, or attention controls.

BACKGROUND

Description of the condition

Stroke is broadly characterised as a condition of neurological dysfunction caused by an acute focal vascular injury in the central nervous system, either ischaemic or haemorrhagic, based on pathological, imaging, or clinical evidence [1, 2]. Globally, stroke is the second leading cause of death and the third cause of combined death and disability, indicated by the disability-adjusted life-years (DALYs) lost [3]. According to the Global Burden of Disease (GBD) Study 2019, there were 12.2 million incident strokes, 101 million prevalent strokes, 6.55 million deaths, and 143 million DALYs attributable to stroke worldwide [4]. Due to advancements in emergency and acute care technologies, the age-standardised incidence and mortality of stroke have decreased substantially; by 17% (incidence) and 36% (mortality) from 1990 to 2019 [4]. Despite these advancements in stroke prevention and care, the financial burden of stroke treatment and care remains substantial. The costs associated with the stroke care continuum vary significantly across countries, with global average expenditures ranging from approximately USD 660 to USD 239,000 [5]. According to a report by an American Heart Association working group, the annual direct healthcare costs related to stroke in the United States are projected to increase by more than 150%, from USD 71.55 billion in 2012 to USD 183.13 billion by 2030 [6]. Considering the high prevalence and substantial economic burden induced by stroke-related healthcare, it is crucial to explore effective strategies for the management of post-stroke consequences.

Stroke survivors may face various degrees and combinations of physical, cognitive, or communication impairments that affect their ability to perform daily activities independently. The China Stroke Surveillance Report 2021 indicated that approximately 12.5% of stroke survivors in China were left disabled, equating to 2.2 million with stroke-related disabilities in 2020 [7]. Based on data from the 2019 Swedish Stroke Register, Sennfalt and colleagues found that five years after stroke, 79% of people with ischaemic stroke and 70.6% of those with intracerebral haemorrhage were dead or dependent [8]. Functional disabilities may also lead to a wide range of psychological challenges, such as increased emotional distress and social difficulties. This includes restrictions in social participation for survivors across various stages of their stroke recovery [9, 10]. Approximately 30% to 50% of survivors may develop depressive symptoms within the first five years after their stroke [11, 12], which may exacerbate their functional dependence [13]. These physical and psychosocial disturbances may further reduce stroke survivors' quality of life and subjective well-being [10, 14], and increase the risk of all-cause mortality [15].

Because stroke survivors often face long-lasting and interrelated physical and psychosocial disturbances, they may require both immediate and continuous recovery and rehabilitation management throughout their stroke trajectory. Recent literature has emphasised the importance of psychological factors, such as the role of motivation and self-efficacy, in recovery and adaptation to life challenges for people after stroke [16, 17]. Motivation plays a key role in encouraging purposeful action. It is traditionally classified as intrinsic motivation, driven by internal desires (e.g. personal values and goals), and extrinsic motivation, influenced by external rewards or the desire to please others, such as family members or therapists [18, 19]. Extrinsic motivation strategies, such as monetary incentives or rewards from family members,

can effectively promote rehabilitation and behavioural changes, and improve psychological wellbeing in survivors in the early post-stroke stage [19, 20]. Intrinsic motivation ensures that a person's behaviour aligns with their personal values and goals, facilitating the sustained pursuit of target behaviours [21]. Stroke survivors' intrinsic motivation may be moderately correlated with improvements in functional independence [22]. Fu and colleagues tested a community-based, self-directed rehabilitation intervention designed to stimulate intrinsic motivation by fostering senses of purpose, hope, and enhanced autonomy. This approach led to substantial improvements in quality of life, independence, and participation for stroke survivors [23]. As a result, it is important to consider effective psychological strategies to enhance stroke survivors' intrinsic motivation in stroke rehabilitation and recovery, ultimately improving functional and psychosocial outcomes.

Description of the intervention and how it might work

Motivational interviewing (MI) is a potentially important approach to enhance a person's intrinsic motivation to facilitate behaviour change [24]. MI is a directive, client-centred counselling approach that enhances personal commitment to behaviour changes by exploring and resolving ambivalence within an environment of acceptance and compassion [25, 26]. The main principles of MI encompass expressing empathy, developing discrepancy, rolling with resistance, and supporting self-efficacy [27]. Several core techniques and skills can be flexibly used, including asking open questions, affirmation, reflective listening, summarising the situation, and informing and advising [26, 28]. MI works through four key processes, including (1) engaging clients in a working partnership; (2) focusing on specific directions for behaviour changes; (3) evoking intrinsic motivations for behaviour changes; and (4) planning reasonable action plans towards behaviour changes [26, 28].

MI interventions aim to help individuals identify and resolve discrepancies between their desired and actual behaviours, and evoke their reasons for change, thus minimising resistance and enhancing intrinsic motivation for behaviour changes [24]. Originally developed to address alcohol addiction behaviours [29], MI interventions have increasingly been applied to manage a variety of problematic behaviours, including smoking [30], and non-adherence in the management of chronic conditions [31]. Adhering to its core principles and skills, MI has been flexibly adapted to include single or multiple brief consultation sessions lasting 5 to 15 minutes, often combined with additional techniques, such as feedback [24, 32]. A widely used adaptation of MI is motivational enhancement therapy, a standardised, multi-session intervention that encompasses an extensive assessment, personalised feedback, and follow-up interviews [32, 33]. Moreover, MI can be used as a standalone intervention, or as a prelude to, or integrated with other treatments, such as inpatient care or cognitive behavioural therapy [32, 34]. MI can be administered by trained practitioners from diverse professions (e.g. medical providers) across various clinical settings, such as general hospital wards and medical clinics [34]. Results from previous systematic reviews suggest that the effectiveness of MI may vary in intervention characteristics, such as delivery modes (e.g. individual or group) and practitioner qualifications [30, 31, 35, 36]. For instance, using meta-regression, VanBuskirk and Wetherell found that the effect of MI on health behaviour enhancement appears to increase as the professional qualifications of the

practitioners rise (e.g. from a research assistant to a master's-level counsellor [36]). Several reviews found that MI delivered by lay healthcare workers or nurses significantly improved health behaviours, including medication adherence and smoking cessation, while MI delivered by psychologists or physicians showed non-significant results [30, 31]. Huang and colleagues showed that MI in mixed formats (combining group and individual sessions) slightly outperformed individual formats in symptom management, including the reduction of diastolic blood pressure [35]; whereas Palacio and colleagues found that MI delivered in group format improved medication adherence, but not when delivered individually or in mixed formats [31]. Therefore, it is essential to consider intervention characteristics when exploring the effectiveness of MI.

Although the mechanisms underlying the effectiveness of MI are not fully understood, MI-based interventions have proven effective by carefully considering and applying MI's key principles, techniques, and core processes. There are three hypotheses about the therapeutic mechanisms of MI: the technical hypothesis, the relational hypothesis, and the conflict resolution hypothesis [37]. The technical hypothesis asserts that the effectiveness of MI depends largely on the therapists' skills in using MI-consistent techniques (e.g. reflective listening, open-ended questions) to encourage clients' engagement in change talk [38, 39, 40]. The relational hypothesis underscores the importance of the humanistic spirit (e.g. therapist's expression of empathy) in the effectiveness of MI. However, Frey and colleagues noted that successfully achieving desired outcomes relies on both creating a supportive communication environment and proficiently employing specific techniques outlined by the technique hypothesis [41]. The conflict resolution hypothesis emphasises the impact of effectively exploring and resolving client ambivalence from both sides—increasing 'change talk' and decreasing 'sustain talk'—throughout the course of a helping relationship [41].

Many studies have also explored the elements and factors associated with the effectiveness of MI. A systematic review examining the MI mechanisms in relation to health behaviours identified the spirit of MI (including collaboration, evoking clients' ideas about change, and promoting autonomy) and clients' motivation as promising factors [42]. Clients' active engagement in change talk and discrepancy development are crucial elements that make MI effective for behaviour changes [43, 44]. MI can engage clients at various stages of readiness for behaviour change, including those ambivalent or unprepared, and enhance their psychological preparedness in managing difficulties by establishing realistic goals and boosting self-efficacy [38, 45].

Why it is important to do this review

To date, it has been suggested that MI is effective in promoting health-related behavioural changes and quality of life in people with chronic conditions, such as diabetes [46], heart failure [47], and stroke [48]. For stroke survivors, several existing reviews have synthesised evidence of MI interventions. However, few of them comprehensively and systematically examined the evidence on functional and psychosocial outcomes. A recent meta-analysis reviewed six randomised controlled trials (RCTs) to assess the effects of MI on depression, anxiety, and quality of life in stroke survivors [49]. The results of meta-analyses found significant improvements in depression and quality of life at 12-month follow-

up, but non-significant reduction in anxiety. However, this review excluded studies with incomplete data and was limited to studies published only in English and Chinese. Potter and colleagues reviewed the evidence of integrating MI or cognitive interventions, or both, with physical therapy on physical outcomes (e.g. mobility) among stroke survivors [50]. However, including studies that combined MI with other treatments, such as cognitive therapy, made it difficult to isolate the specific effects of MI alone. A previous Cochrane review explored the effects of MI on stroke survivors [33]. This review searched studies published up to 2015, and included only one RCT that assessed the effects of MI on stroke survivors' activities of daily living, mood, and death. Due to the limited number of studies included, the evidence was insufficient to conclusively determine the benefits of MI for stroke survivors.

Since the last review in 2015, we anticipate that more RCTs examining the effects of MI for stroke survivors have been completed. We updated the protocol to synthesise the latest evidence, and to focus on more comprehensive outcomes for stroke survivors, including both functional and psychosocial aspects. We will also adopt the new risk of bias tool (RoB 2), and use the GRADE approach to evaluate the certainty of evidence derived from this updated review, reflecting advancements in methodology.

OBJECTIVES

To evaluate the benefits and harms of motivational interviewing for functional and psychosocial outcomes in stroke survivors, compared to no intervention, waiting list, or attention controls.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) with parallel group designs, including cluster-RCTs and cross-over RCTs. However, for cross-over studies, we will only use data from the first phase for analysis to avoid potential carry-over effects.

We will exclude observational studies, non-randomised, or quasi-experimental trials (any quantitative study estimating the effectiveness of an intervention that does not use randomisation to assign individuals or clusters of individuals to intervention groups), and research letters.

We will include studies reported in full text and those published as abstracts, provided they include a clear description of study details (including interventions and methods) to confirm their eligibility for inclusion. There are no restrictions on the language, year of publication, or duration of follow-up.

Types of participants

We will include studies that include post-stroke survivors (aged 18 years or older) in diverse settings, including hospitals, rehabilitation facilities, or communities. Stroke can encompass ischaemic, haemorrhagic (e.g. intraventricular, intracerebral, or spontaneous subarachnoid haemorrhage), uncertain pathological subtypes, or mixed types, with a diagnosis based on criteria from the World Health Organization [1], the American Heart Association [2], or other similar diagnostic guidelines. There are no restrictions on stroke stages or severity, or whether it is a first or recurrent

occurrence. There are also no restrictions on participants' ethnicity or cultural background.

We will exclude studies that include participants with mixed aetiologies, such as stroke and traumatic brain injuries, unless they provide separate results for the stroke participants of interest.

The successful implementation of motivational interviewing (MI) relies heavily on participants' cognitive and language skills. However, stroke survivors may experience one or more cognitive impairments, such as aphasia, executive function deficits, and reduced memory and information processing abilities. To minimise participant variability and a biased evaluation of MI in stroke survivors, we will only include studies that explicitly exclude individuals with severe cognitive or language impairments that prevent them from comprehending and following the intervention instructions.

Types of interventions

We will include motivational interventions labelled as motivational interviewing or motivational enhancement therapy if they conform to the principles and techniques of MI (e.g. exploring ambivalence, eliciting change talk, and supporting self-efficacy), described by Miller and Rollnick [26, 27].

For studies that involve multi-component interventions, we will include those in which the additional interventions are identical across both experimental and control conditions, i.e. the MI component is the only difference between the groups.

We will include interventions delivered in either individual or group formats, through face-to-face, remote (e.g. telephone, online video call), or hybrid modes. However, the interventions should be delivered by a person, not through machine or robot-based methods. There are no restrictions on the number of sessions or duration of the interventions.

Comparators will be: no intervention, waiting list (i.e. control group receiving the intervention post-study), or attention controls (i.e. an active control arm without any specific psychological intervention).

Outcome measures

This review will focus on the functional and psychosocial outcomes of stroke survivors. Psychosocial outcomes will encompass a range of cognitive (e.g. self-efficacy, motivation), emotional (e.g. depression, anxiety), social (e.g. social participation, social support), and behavioural changes (e.g. medication adherence, lifestyle behaviours), as well as broad and aggregated measures of general mental health and quality of life, which reflect individuals' psychological and social functioning [51]. However, we will not include biological markers (e.g. blood pressure, blood glucose, or cholesterol levels) or economic outcomes (e.g. income and financial burden) in this review.

We will not exclude studies if they fail to report one or several of the prespecified functional or psychosocial outcomes, or if they measure these outcomes but do not report the data, or present them in an unusable format. For outcomes measured with multiple scales, we will prioritise the measures according to the order listed in the [Critical outcomes](#) and [Important outcomes](#) sections to reduce the risk of selective outcome reporting.

We will record and present all outcome assessments at different intervals from the end of the intervention, as reported in each study, and categorise them into three sets of time points: short-term (up to one month post-intervention), medium-term (one to six months post-intervention), and long-term (beyond six months post-intervention), based on criteria from previous literature on psychological interventions for people with chronic conditions [52, 53, 54]. If an outcome is reported multiple times within a category, we will prioritise the latest time point in that category for data synthesis, to minimise the selective reporting bias (e.g. if measures are reported at three months and six months post-intervention, we will use the results at six months for medium-term effects).

Critical outcomes

We will consider these critical outcomes.

- **Functional independence:** any validated measures, such as the Functional Independence Measure [55], modified Rankin Scale [56], Barthel Index [56], and the World Health Organization Disability Assessment Schedule [57]
- **Depression:** any validated measures, such as the Patient Health Questionnaire-9 [58], Hamilton Depression Rating Scale [59], 10-item Center for Epidemiological Studies Short Depression Scale [60], Beck's Depression Inventory [60], Hospital Anxiety and Depression Scale, and the Geriatric Depression Scale [60]
- **Health-related quality of life:** any validated measures, such as the Stroke Impact Scale [61], Stroke Specific Quality of Life Scale [62], Burden of Stroke Scale [61], 36-Item Short-Form Health Survey [63], EuroQol five-dimension questionnaire [64], World Health Organization Quality of Life Assessment [65], and the World Health Organization Quality of Life - BREF [66]

Important outcomes

We will consider these important outcomes.

- **Medication adherence:** any validated measures of individuals' adherence to medication intake, such as the Morisky Medication Adherence Scale, Hill-Bone Compliance Scale, and the Brief Medication Questionnaire, as well as objective measures, such as pill counting [67]
- **Social participation:** any validated measures of social activities, such as the Impact on Participation and Autonomy, Assessment of Life Habits, Frenchay Activities Index, and the Activity Card Sort [68]
- **Adverse events:** the number of participants reporting a worsening of medical conditions (e.g. recurrent stroke, cardiovascular events, or falls), rehospitalisation, suicide attempts, suicides, death from any cause, or other crises [69]
- **Motivation:** any validated measure of the desire to act towards a goal, such as the Intrinsic Motivation Inventory, Adapted Achievement Motivation Questionnaire, Questionnaire for Current Motivation, and the Stroke Rehabilitation Motivation Scale [70]
- **Self-efficacy:** any validated measures of beliefs and perceptions regarding one's ability to exert control over his/her motivation, behaviour, and social environment, such as the Stroke Self-efficacy Questionnaire [71], General Self-efficacy Scale [72], Participation Strategies Self-efficacy Scale, and the Self-efficacy for Exercise Scale [71]

- **Social support:** any validated measures of support from families and friends, such as the Social Support Questionnaire [73], and the Duke Social Support and Stress Scale [74]
- **Lifestyle behaviours:** any measure of participants' changes in lifestyle behaviours that influence stroke recurrence and functional deterioration, including smoking behaviours, physical activity (e.g. volume, duration), and dietary behaviours
- **Motor function:** any validated measures of motor functioning and performance, such as the Fugl-Meyer assessment, Wolf Motor Function Test, Timed Up and Go, 10-metre Walk Test, and the Motor Activity Log [75, 76]
- **Anxiety:** any validated measures, such as the Generalised Anxiety Disorder Questionnaire, Beck Anxiety Inventory, Hamilton Anxiety Scale, State Trait Anxiety Inventory, and the Hospital Anxiety and Depression Scale [77]
- **Mental health:** any validated measures of overall mental health conditions, such as the 28-item General Health Questionnaire [78]
- **Satisfaction:** any measure of participant-reported satisfaction with the intervention, defined by the study authors

Search methods for identification of studies

We will adopt the following methods to identify studies for this review.

Electronic searches

We will search the following sources from the inception of each database to the date of search, and will place no restrictions on the language of publication:

- Cochrane Central Register of Controlled Trials (CENTRAL; current version) in the Cochrane Library (search date);
- MEDLINE OvidSP (1946 to search date);
- Embase OvidSP (1974 to search date);
- APA PsycINFO OvidSP (1806 to search date);
- CINAHL Complete EBSCOhost (1937 to search date);
- SinoMed (www.sinomed.ac.cn; 1978 to search date);
- China Network Knowledge Infrastructure (CNKI; www.cnki.net; 1915 to search date);
- Wanfang Data (www.wanfangdata.com.cn; 1985 to search date);
- Chinese Scientific Journals Database (VIP; www.cqvip.com; 1989 to search date);
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov; search date)
- ISRCTN Registry (www.isrctn.com; search date);
- World Health Organization International Clinical Trials Registry Platform (ICTRP; www.who.int/trialsearch/; search date).

The details of the search strategies can be found in [Supplementary material 1](#). They are consistent with the strategies used in the 2015 review [33]. We will use published and validated search filters to identify randomised trials in the MEDLINE, Embase, and CINAHL databases according to Chapter 4 of the *Cochrane Handbook for Systematic Reviews of Interventions* [79, 80, 81].

Searching other resources

We will review the references of all identified studies and relevant systematic reviews (identified through the electronic searches),

as well as grey literature, to seek additional RCTs that may be eligible for inclusion. We will contact the authors of registered but incomplete trials to enquire about their progress, anticipated completion dates, and any published or unpublished study results.

Data collection and analysis

We will follow the standard procedure of study selection, data extraction, and evidence synthesis, in accordance with the *Cochrane Handbook* [82].

Selection of studies

Two review authors (of HYM, HYC, SHSL, MWMC) will independently screen the titles and abstracts of all identified citations for potential relevance. Then, they will retrieve the full-text publications of all potentially eligible citations. Two review authors (of HYM, HYC, SHSL, MWMC) will independently assess the full texts based on the pre-determined eligibility criteria. For studies with unclear eligibility details, we will contact the authors for clarification. Any disagreements will be resolved through discussion, or if necessary, by consulting a third review author (WTC). To ensure transparency, we will selectively document reasons for excluding studies (e.g. those that initially appear eligible, or we anticipate to be of interest to readers) in the characteristics of excluded studies table.

For studies with multiple reports, we will collate them into a single study with a unique identifier linked to multiple references, ensuring that each study, rather than each report, is the unit of interest in the review. For those published in languages other than English or Chinese, we will assess their eligibility using translation tools, or by involving translators familiar with the publication language, obtained through our networks or via Cochrane Engage.

We will clearly outline the study selection process in a PRISMA flow diagram [83]. We will use Covidence software to complete the process [84].

Data extraction and management

Two review authors (of HYM, HYC, SHSL, MWMC) will independently extract data from the included studies using a prespecified data extraction form in Covidence software [84]. This form will be pilot tested in two studies, and revised as necessary, before being used in the formal data extraction process. For each included study, they will extract these details.

- **Methods:** including study design, allocation method, blinding, intention-to-treat principle, and setting
- **Participants:** including age, gender, diagnosis type, stroke history, eligibility criteria, comparison of baseline characteristics, number randomised, number analysed, intervention completion rate, and dropout rate
- **Interventions** (and control conditions where applicable), based on the COMPASS checklist [85]: including intervention content, theoretical framework and mechanism, duration, frequency, delivery mode, and practitioners
- **Outcomes:** including measures and time of assessment
- **Notes:** including date, country, registration, funding, notable conflicts of interest of trial authors, and any adverse effects documented

We will contact study authors to provide additional (unpublished) relevant information if necessary. We will resolve disagreements

by discussion, or if necessary, by consulting a third review author (WTC). We will translate study reports that are not in English or Chinese using translation tools or translators obtained through our networks or Cochrane Engage.

One review author (HYM) will transfer data to RevMan [86]; a second review author (MWMC) will cross-check the data entry.

Risk of bias assessment in included studies

The risk of bias assessment will focus on the six most important outcomes listed in the summary of findings table: functional independence, depression, health-related quality of life, medication adherence, social participation, and adverse events, at medium-term follow-up. We will prioritise medium-term follow-up effect estimates in the summary of findings table, as participants need time to integrate psychological and behavioural changes into their daily lives, thereby enhancing their functional and psychosocial outcomes. Two review authors (HYM and MWMC), with expertise in stroke care and risk of bias methodology, will independently carry out the assessment using the Cochrane RoB 2 tool, implemented through the RoB 2 Excel tool, available on the riskofbiasinfo.org website [87, 88]. They will pilot test the RoB 2 tool in three studies before the formal assessment, to ensure a proper understanding of the tool, and to improve the reliability and consensus of the evaluations. If there is insufficient information about study methods or outcomes to assess the risk of bias, the review authors (HYM and WMC) will contact the study authors for clarification. Any disagreements will be resolved through discussion, or by consulting a third review author (MWTC).

The RoB 2 tool assesses the risk of bias for individual RCTs across the following five domains:

- Bias arising from the randomisation process;
- Bias due to deviations from intended interventions (assessing the effect of assignment to intervention);
- Bias due to missing outcome data;
- Bias in measurement of the outcome; and
- Bias in selection of the reported result.

Each domain is addressed by answering a series of signalling questions. Responses to these questions will be processed through an algorithm, which results in a domain-level judgment, categorised as low risk of bias, some concerns, or high risk of bias. These domain-level judgments will collectively contribute to an overall risk of bias assessment for the outcome in each study.

- Low risk of bias: all domains are judged to be at low risk of bias
- Some concerns: at least one domain is judged to raise some concerns, and none of the domains are considered at high risk of bias
- High risk of bias: at least one domain is judged to be at high risk of bias

Cluster- and cross-over trials appear to be rare for the topic of interest. If we identify any cluster-RCTs, we will assess their risk of bias using the RoB 2 tool for cluster-randomised trials, adding a domain to assess the risk of bias arising from the timing of identification and recruitment of participants [89]. For cross-over trials, we will use the RoB 2 tool for randomised cross-over trials, adding a domain to assess the risk of bias from period and carry-over effects in a cross-over trial [89].

We will present a summary figure of the risk of bias assessments and integrate these results into our evaluation of the certainty of evidence. We will also provide the reasons for algorithm-proposed judgments in the supplemental material, using quotes from the study report.

Measures of treatment effect

For dichotomous outcomes, we will calculate the risk ratios (RRs) with 95% confidence intervals (CIs). If individual studies report adjusted odds ratios (ORs) with corresponding CIs and do not provide raw contingency tables, we will pool ORs instead of RRs, using the generic inverse-variance method. For continuous outcomes, we will preferably calculate the standardised mean differences (SMDs) with 95% CIs, considering the high probability of different outcome measures used across included studies. The effect size will be interpreted based on the values of the SMD: 0.2 represents a small effect, 0.5 a moderate effect, and 0.8 a large effect [90, 91].

We will input data presented with a consistent direction of effect across studies. We will primarily use endpoint data to compute effects, and will resort to changes from baseline data only if endpoint data are unavailable. If necessary, we will merge endpoint and change data in the meta-analysis when the MD of outcomes, rather than SMD, is available and appropriate for use [92]. If data are not presented in a format suitable for direct entry into meta-analysis, we will convert them to the required format, based on the guidance in Chapter 6 of the *Cochrane Handbook* [93]. We will use RevMan to conduct the analyses [86].

Unit of analysis issues

The unit of analysis will be the individual participant. We will deal with special unit of analysis issues (e.g. cluster-RCTs, cross-over studies, and multi-arm studies) following the guidance in Section 6.2 of the *Cochrane Handbook* [93].

If we include data in meta-analysis from both cluster-RCTs and individual RCTs, we will consider using the intraclass correlation coefficient (ICC) to adjust studies to effective sample sizes for precise and valid weighting of studies across diverse designs.

For cross-over trials, we will use only the data from the first phase (before the cross-over), considering the potential carry-over effects.

For multi-arm studies, we will combine the intervention groups relevant to this review topic into a single pairwise comparison for each study, ensuring no double-counting occurs. We will describe the irrelevant groups in the characteristics of included studies table, but will exclude them from any analysis.

For outcome data measured repeatedly at different time points, we will categorise the follow-up periods into short-, medium-, and long-term. If an outcome is reported multiple times within a category, we will prioritise the latest time point in that category for data synthesis to minimise the selective reporting bias (see [Outcome measures](#)).

Dealing with missing data

For unreported or missing data in a study, we will contact the study authors to request the information. If the requested data are unavailable, we will document the missing details in the

characteristics of included studies table, and follow the *Cochrane Handbook* guidelines for dealing with missing data [92, 93].

We will use intention-to-treat (ITT) data whenever possible, and resort to completer data analyses only if ITT data are unavailable. If feasible, we will estimate missing SDs or other necessary data using study information, such as standard errors, P values, or CIs. For studies in which the SD of the outcome is unavailable at follow-up, or cannot be re-estimated, we will use the means of the pooled baseline SDs from studies that reported this information.

We will evaluate this issue in the 'missing outcome data' domain of RoB 2, and conduct a sensitivity analysis by excluding studies in which missing data exceed 50% during the longest follow-up period. We will discuss the potential impact of missing data on the review's findings in the Discussion section.

Reporting bias assessment

We will attempt to obtain and compare study protocols with published reports to identify the presence of selective outcome reporting. If the full protocol is unavailable, we will compare the information listed in trial registries (when available) or the Methods section of the published report with the results that are actually reported.

If at least 10 studies are included in a single meta-analysis, we will create a funnel plot to explore the potential publication bias [89, 94], and conduct formal statistical tests to assess funnel plot asymmetry [95].

As noted in the [Risk of bias assessment in included studies](#), we will consider outcome selective reporting in the risk of bias assessment for the outcomes listed in the summary of findings table.

Synthesis methods

We will consider the comparison between MI delivered in any form (e.g. face-to-face or online mode, individual or group format) and a control group (including no intervention, waiting list, or attention controls). We will undertake meta-analyses when data are available from at least two studies that show sufficient similarity in interventions, participants, and underlying clinical questions. The primary meta-analysis will include all eligible studies, regardless of their risk of bias. All meta-analyses will be undertaken using RevMan [86], and presented using forest plots, in accordance with the *Cochrane Handbook* [92].

We will use a random-effects model for all meta-analyses, due to the high likelihood of heterogeneous study characteristics (e.g. participants, interventions, and outcome measures) across different studies, even in the absence of statistically significant heterogeneity. We will use the Mantel-Haenszel method to pool dichotomous outcomes, and the inverse-variance method to pool continuous outcomes.

If we judge meta-analysis inappropriate due to significant unexplainable heterogeneity among studies, or limited data availability, we will summarise the results narratively following the Synthesis Without Meta-analysis (SWiM) approach [96].

Investigation of heterogeneity and subgroup analysis

We will assess clinical and methodological heterogeneity when pooling studies in a meta-analysis. For meta-analyses, we will

assess statistical heterogeneity by visually inspecting the forest plots and using I^2 and χ^2 statistics. The statistical heterogeneity will be interpreted based on the range of the I^2 statistic: 0% to 40% might not be important; 30% to 60% may suggest moderate heterogeneity; 50% to 90% may indicate substantial heterogeneity; and 75% to 100% signifies considerable heterogeneity. If we identify considerable heterogeneity (e.g., $I^2 \geq 75\%$), we will investigate possible causes by comparing the characteristics of each study, and undertaking subgroup analyses where feasible, or narratively summarising the results [92].

If we identify at least 10 studies, we will conduct subgroup analyses to explore sources of heterogeneity in intervention and health inequity characteristics.

- Delivery mode of intervention (e.g. individual, group, or mixed)
- Practitioner qualification (e.g. psychologists, physicians, nurses, or others)
- Study location (e.g. high-, middle-, or low-income countries)
- Race (e.g. African or Black populations, Caucasian or White populations, Asian populations, Hispanic or Latino populations, others)

We will interpret the results cautiously because of the possible confounding by other study characteristics [92]. If we identify any initially overlooked characteristics that are crucial for subgroup analysis, we will include them post hoc, and document the reasons for our decision.

Equity-related assessment

We will investigate health inequities with a focus on two characteristics defined by PROGRESS-Plus [97]: place of residence and race/ethnicity/culture. Disparities in stroke epidemiology and its care vary significantly across high-, middle-, and low-income countries, influenced by socioeconomic status and the availability of healthcare professionals [98]. We will use the countries in which the trial was conducted as a proxy for the participants' place of residence. Individuals from different racial/ethnic and cultural minorities may have disproportionate access to mental health services and hold different attitudes towards these services, including motivational interviewing [99, 100].

Sensitivity analysis

To assess the robustness of our review findings, we will conduct sensitivity analyses on the critical outcomes by excluding studies that meet the following criteria, assuming we have sufficient data.

- Studies rated at high overall risk of bias
- Studies with dropout rates exceeding 50% during the longest follow-up period (refer to the [Dealing with missing data](#))
- Studies that incorporate pre-to-post mean change scores in the meta-analyses (only for those analyses that combine endpoint scores with change scores for continuous outcomes)

If these sensitivity analyses reveal significant differences in the direction or precision of effect estimates, we will consider that the effects are sensitive to these factors and will thoroughly discuss them in the Discussion section.

Certainty of the evidence assessment

We will create a summary of findings table to present the results of the comparisons between MI and the control groups (e.g. no intervention, waiting list, or attention control) for stroke survivors, according to Chapter 14 of the *Cochrane Handbook* [101]. The summary of findings table will include the most important six outcomes, measured at medium-term follow-up (one to six months post-intervention). The SMD obtained from the meta-analyses will be converted into predefined measures as detailed below, to ensure clear and accurate representation of effect sizes.

- Functional independence, presented using the Functional Independence Measure
- Depression, presented using the Patient Health Questionnaire-9
- Health-related quality of life, presented using the Stroke Impact Scale
- Medication adherence, presented using the Morisky Medication Adherence Scale
- Social participation, presented using the Impact on Participation and Autonomy
- Adverse events, participants reporting a worsening medical condition

If a meta-analysis is not possible, we will present the results narratively in the summary of findings table, based on the GRADE guidelines for informative statements [102].

We will use the GRADE approach to assess the certainty of evidence in the summary of findings table across five domains: overall risk of bias, inconsistency, indirectness, imprecision, and publication bias [103]. The overall certainty of evidence for each outcome will be judged as high, moderate, low, or very low certainty.

Two review authors (HYM and MWM) will independently conduct the assessment of evidence certainty. Any discrepancies will be resolved through discussion or by consulting a third review author (WTC). We will use GRADEpro GDT software [104], and follow the methods and recommendations outlined in Chapter 14 of the *Cochrane Handbook* [101, 103].

Consumer involvement

Due to time and resource constraints, the review team was unable to involve consumers in the development of this protocol. However, in the review process, two service users (i.e. stroke survivors) will serve as advisors to provide feedback on the presentation and interpretation of our results, and assist in creating key messages for disseminating our findings.

SUPPLEMENTARY MATERIALS

Supplementary materials are available with the online version of this article: [10.1002/14651858.CD016110](https://doi.org/10.1002/14651858.CD016110).

Supplementary material 1 Search strategies

ADDITIONAL INFORMATION

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Editorial and peer-reviewer contributions

The following people conducted the editorial process for this article:

- Sign-off Editor (final editorial decision): Derek T Wade, Oxford Brookes University, Oxford, UK;
- Managing Editor (selected peer reviewers, provided editorial guidance to authors, edited the article): Justin Mann, Central Editorial Service; Sue Marcus, Central Editorial Service
- Editorial Assistant (conducted editorial policy checks, collated peer-reviewer comments and supported editorial team): Jessenia Hernandez, Central Editorial Service;
- Copy Editor (copy editing and production): Victoria Pennick, Cochrane Central Production Service;
- Peer-reviewers (provided comments and recommended an editorial decision): Harry Karel McNaughton, Medical Research Institute of New Zealand (clinical/content review)*, Edozie Iweka, University Hospitals of Derby and Burton NHS Foundation Trust, United Kingdom (consumer review), Clare Miles, Evidence Production and Methods Directorate (methods review), Joanne Platt, Central Editorial Information Specialist (search review).

Contributions of authors

Huanyu Mou initiated this project and wrote the protocol.

Wai Tong Chien, Ho Yu Cheng, Suzanne Hoi Shan Lo, Mimi Wai Man Chan, Shanshan Kong, and Kai Chow Choi reviewed and drafted parts of the protocol.

Declarations of interest

Huanyu Mou has declared that she has no conflict of interest.

Wai Tong Chien is an editor with Cochrane Hong Kong; he has declared that he has no conflict of interest. He was not involved in the editorial process as an editor, since he is one of the authors of this review.

Ho Yu Cheng has declared that she has no conflict of interest.

Suzanne Hoi Shan Lo has declared that she has no conflict of interest.

Mimi Wai Man Chan has declared that she has no conflict of interest.

Shanshan Kong has declared that she has no conflict of interest.

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- The Nethersole School of Nursing, the Chinese University of Hong Kong, Hong Kong

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External sources

- None, Other

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Registration and protocol

In protocols: Cochrane approved the proposal for this review update in January 2024.

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Data, code and other materials

None.

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