Project Title
Mindfulness-based interventions for people with recent-onset psychosis: a randomized controlled trial in Hong Kong.

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Introduction

Psychotic disorders include severe mental illnesses that affect a person's activities of daily living in terms of cognitive function, interpersonal relationships, personal self-care and occupational functioning. Symptoms of psychotic disorders such as schizophrenia include delusions, hallucinations, disorganized thinking and or speech, grossly disorganized or abnormal motor behavior and negative symptoms such as diminished emotional expression and avolition. Psychotic disorders are heterogeneous in their presentation and disabling lifelong illnesses with a lifetime prevalence of approximately 0.2 – 9% (American Psychiatric Association, 2013). The development of illness may appear in adolescent or early adulthood, and onset can occur across the lifespan.

Concurrently with positive and negative symptoms, affective symptoms and full affective disorder episodes are common in psychotic disorders particularly in the acute phase of illness. Affective symptoms are a significant risk factor accounting for approximately 5-6% of suicide rates which remain or becomes higher shortly after a psychotic episode or hospital discharge (American Psychiatric Association, 2013). O'Driscoll, Laing and Mason (2014) have reviewed 47 case-control studies and observed the emotion management (Hedges' g=0.96; 95% CI) and cognitive reappraisal (Hedges' g=0.49; 95% CI) were negatively associated with schizophrenia. People with schizophrenia demonstrated a tendency to use maladaptive cognitive emotion regulation strategies as compared with healthy control groups. The review suggested that emotion regulation has a significant role in managing distress related to psychotic symptoms and interventions that include emotion regulation skills training and psychoeducation, as observed in mindfulness approaches may be a promising approach for emotion regulation in people with psychosis.

The present study is the first randomized controlled trial of group mindfulness-based intervention for psychosis. We hypothesize that mindfulness will have a positive impact on emotion regulation and distress and in so doing this will have a positive impact on psychotic symptoms, quality of life and re-hospitalization. The primary outcome will be a measure of emotional distress. The primary hypothesis will be group Mindfulness-based Cognitive Therapy for Psychosis (MBCTp) plus treatment-as-usual (TAU), in comparison to active control group psychoeducation plus TAU, will lead to adaptive processing of emotion in people with psychotic disorders and consequently alleviate distress in response to psychotic symptoms.

Management of psychosis

According to Chien and Yip's (2013) comparative review of the current pharmacological, medical treatments and psychosocial interventions for schizophrenia, first –and /or second-generation antipsychotics have remained the first-line medical treatment for psychosis. Such interventions have shown to be effective in reducing overall psychotic symptoms and relapse in patients with schizophrenia, at least in the short-term or at the acute stage of illness. However, the use of antipsychotics alone has its limitations in tackling the frequency of negative symptoms, cognitive impairments, stressful life events and psychological distress, as well as those illness-related and drug-induced problems such as weight gain. It has been recommended that psychological or psychosocial interventions should be considered as an adjunct to antipsychotic agents such as cognitive therapy, psychoeducation, family intervention, social skills training and assertive

community treatment (The National Institute For Health and Care Excellence, 2014). Application of such interventions to people with psychosis has shown satisfactory levels of short- to medium-term clinical efficacy in terms of symptom control or reduction, level of functioning, and/or relapse rate (Chien, Leung, Yeung and Wong, 2013) when used alongside antipsychotics.

Timely interventions to the early phase of psychotic disorders might offer an opportunity to lessen treatment costs over the first few years of course of illness and impacts of positive and negative symptoms to daily living (Mihalopoulos et al, 2009; Valmaggia et al, 2009). The National Institute For Health and Care Excellence (2014) has also revised the management protocol and suggested extending the early intervention in psychosis treatment regime beyond 3 years, if people with psychosis have not made a sustained recovery.

Psychosis and emotion regulation

Emotion regulation refers to the processes describing how individuals respond when they experience emotions, and by which, individuals may increase, maintain and decrease negative and positive emotions. The regulation emphasizes self-regulation in both conscious and unconscious awareness (Gross, 1998).

Recent research indicates that individuals with psychosis present with high levels of emotional deregulation including depression and anxiety, which could exacerbate their distress induced by psychotic symptoms (Conrad et al, 2014). Research has shown that several months after an acute episode of psychosis, rates of post-psychotic depression can be up to 50% of cases (Whitehead et al, 2002; Birchwood, 2003). Depression in psychosis has been linked with higher levels of hopelessness and an increased likelihood of suicide (White, McCreery, Gumley and Mulholland, 2007). Furthermore, the prevalence of co-morbid anxiety disorders in people with psychotic disorders, has been estimated at 30–85% as compared with general population (Pokos and Castle, 2006). Anger is also initially suggested as the emotion that triggers aggressive behavior, and research finds that people who show trait of anger prompt often engage in verbal and physical aggression (Hodgins, 2008; Volavka, 2013).

The stress-vulnerability model of psychosis has well explained the relationship between emotional and symptomatic responses to stress in people at clinical high risk of developing psychosis. Palmier-Claus, Dunn and Lewis (2011) found that people who are developing psychosis may be particularly sensitive to everyday stressors, which could insidiously increase the psychotic symptoms in response to stressful life events in the course of the illness. Social stigma and difficulties to accept the illness particularly during the onset of first psychotic episode seem to create higher emotional distress (Reed, 2008; Corker et al, 2015). Kashdan et al. (2006) proposes that experiential avoidance when it is in higher levels, promotes the production of unwanted distressful experiences and has a higher contribution to psychopathology than the content of psychological symptoms themselves. Psychological flexibility may have a role in general emotional outcome for people with psychotic symptoms (Morris, Garety and Peters, 2014).

The role of psychological interventions on psychotic symptoms and comorbidities

The aim of psychotherapy for psychosis is to reduce relapse rates by reducing symptomatology, improving psychosocial functioning and quality of life, and

strengthening self-esteem. A highly recommended evidence-based intervention is cognitive-behavioral therapy for psychosis which is proved to be effective for reducing positive symptoms by helping people to reappraise thoughts relating to a situation in order to influence the expression and experience of emotions.

Burns, Erickson and Brenner (2014) reviewed 16 randomized controlled trials and 12 of them concluded that Cognitive Behavioural Therapy (Psychosis) (CBTp) is associated with robust improvements in residual distressing positive and negative symptoms and general symptoms of psychotic disorders when it is used as an adjunct psychotherapy. However, CBTp was specifically designed to target positive symptoms and has modest effects but may only have an effect on non-target outcomes except hopelessness, which is closely related to depression and suicide, and showed homogeneity of effect size with negative effects in 3 out of the 4 studies. Wykes, Steel, Everitt and Tarrier (2008) suggest that current CBTp approaches are not proved to benefit hopelessness. However, CBTp has a beneficial impact to the relationship between outcomes which seem to be correlated such as reduction of positive symptoms is negatively related to emotional dysregulation, though the mode of transmission and the timing of such mutual benefits is not clear. There are also fewer studies testing the effectiveness of group therapy with adequate methodology including sample size (Birchwood, 2003; Wykes, Steel, Everitt and Tarrier, 2008).

Mindfulness Intervention for Psychosis

In the past two decades, a number of psychosocial interventions have integrated mindfulness-based strategies for individuals with mental illness. Yet there are only limited randomized-controlled trials on mindfulness interventions for people with psychosis. Khoury and Lecomte (2012) suggested that emotion regulation strategies may play an important role in symptomatic relief and functional outcomes of psychotic disorders such as schizophrenia. Mindfulness-based practice integrated with CBT targeting positive emotions, acceptance, detaching and meta-cognition have been shown to be effective and valuable treatment for positive and negative symptoms, as well as for anxiety and depression (Beck, Rector, Stolar and Grant, 2009; Tai and Turkington, 2009; Chadwick, 2006). A systematic review of mindfulness interventions (MI) for psychosis or schizophrenia done by Khoury et al (2013) has included 13 studies for a comprehensive meta-analysis. It concluded that mindfulness-based treatment is moderately effective in pre-post comparisons of negative and affective symptom, functioning and quality of life, which targeted distress resulting from psychotic symptoms but not the symptoms themselves by changing the relationship to thinking through the cultivation of mindfulness and acceptance (Figure 1). These results also found that the average attrition rate among participants of mindfulness interventions was comparatively lower than of cognitive and behavioural approaches. However, MI approaches varied widely from study to study such as some protocols focus on building acceptance while some emphasize on modifying dysfunctional thought content but have no sophisticated treatment programs and process.

Mindfulness-based interventions with cognitive approaches initially focused on fostering awareness that assists individuals to regard negative thoughts as transient experiences, allow unpleasant psychotic experiences to come into awareness, avoid development of rumination by increasing acceptance and perceiving distress mindfully, ultimately improving clinical functioning and relapse rates (Chadwick

et al, 2005; Chadwick et al, 2009; Langer et al, 2012; Chien & Thompson, 2014). In Chadwick's most recent study (2016), which was the first RCT of group CBTp for voices, there was no significant effect on the primary outcome of psychological distress targeting people with distressing voices in a pragmatic randomized controlled trial. Though there was improvement in intensity of voice distress post-treatment, no effects on depression were found. The generalizability of the study is doubtful across other psychotic symptoms as distressing voices is only one of disturbing symptoms in the course of psychotic disorders.

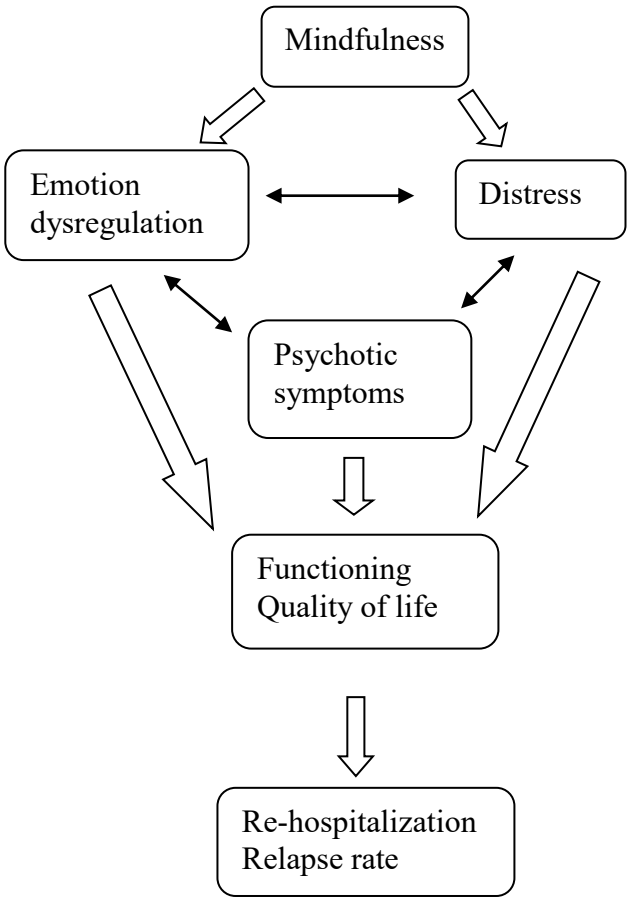

Figure 1 The working mechanism of mindfulness to emotional distress in psychosis

The knowledge gap

Evidence on the effectiveness of mindfulness interventions for psychosis is inconclusive despite that the aforementioned studies have indicated that mindfulness approaches are associated with a decrease in distress, emotional dysregulation and social functioning. Most of the studies had very small number of participants, using non-randomized, non-controlled and inconsistent protocols and process regarding the mindfulness interventions. Particularly, the evidence of mindfulness interventions for regulating emotional dysregulation (such as anxiety, depression and hopelessness) in relation to positive and negative symptoms has not been addressed in the literature.

The knowledge gap is that there is no evidence on whether mindfulness-based intervention can have an effect on emotional distress and emotional regulation in patients with psychosis and subsequently alleviate the positive symptoms of these patients.

Study Aim, Objectives and Hypotheses

The aim of this controlled trial is to test the effectiveness of a mindfulness-based intervention for people with recent-onset psychosis in improving their emotional distress and in so doing this will have a positive effect on positive and negative symptoms, as well as psychosocial functioning.

It is hypothesized that in comparison to routine psychiatric care with Psychoeducation for Psychosis (PEp), the participants receiving Mindfulness-based Cognitive Therapy for Psychosis (MBCTp) will have significantly: -

- Primary outcomes: Decrease in emotional distress at 1-week, 3-month and 6-month follow-ups post-treatment.
- Secondary outcomes: Greater improvements in emotion regulation, psychological flexibility, psychosocial functioning, re-hospitalization rate and psychotic symptoms at 1-week, 3-month and 6-month follow-ups post-treatment.

Method

Design

A randomized controlled trial, using a repeated-measures, two-group design, will be conducted to test and compare the effects of MBCTp in addition to treatment as usual (TAU) and TAU with PEp for people with recent-onset psychotic disorders (according to DSM-V) residing in the community over a 6-month follow-up.

Sampling and study settings

The study will be conducted in Integrated Community Centers for Mental Wellness (ICCMW). The Social Welfare Department has implemented this service in all the districts across the territory since 2010. It aims at enhancing the social support and re-integration of the ex-mentally ill persons into the community. It is a one-stop service providing social rehabilitation services ranging from early prevention to risk management for discharged mental patients, people with suspected mental health problems, their families and carers. There are 26 centers established across the 18 districts in Hong Kong till 2016.

Inclusion criteria:

Participants will be people who were diagnosed with recent-onset psychosis and have follow-up at one of the ICCMW centres;

(i) Participants are Hong Kong Chinese residents and aged above 18;

(ii) Participants have a primary diagnosis of psychosis and/or other psychotic disorders met the Diagnostic and Statistical Manual DSM-V equivalent to or less than 5 years (The National Institute For Health and Care Excellence, 2014);

(iii) Participants are mentally stable as assessed by the researcher and a psychiatrist to comprehend the education and training provided (a pre-recruitment briefing session for potential participants will be conducted to verify their ability to follow instructions and understanding in participation, and case files will be reviewed to ensure a stable medication regime for at least 6 months) in order to ensure their ability to make a valid consent;

(iv) Participants are able to read and understand Cantonese or Chinese.

Exclusion criteria:

(i) Participants have recently participated in (less than 3 months) or are receiving other structured psycho-education and/or psychotherapies;

(ii) Participants have comorbidities (a) developmental impairment (b) learning disability, (c) personality disorders, and/or (d) any clinically significant medical diseases (by case-file review).
(iii) Participants have organic psychosis or a primary drug or alcohol addiction.

Randomisation and recruitment procedure
Participants referred to the study by ICCMW will be assessed at a screening examination to ensure eligibility and obtain written consent by a research assistant. Eligible participants will undertake a further interview on outcome measures prior to randomization within 3 weeks the commencement of intervention. In order to avoid the contamination of participants, participants allocated to either treatment or control groups will be reminded not to share what they have experienced in the group work among members in the service organization. The subjects will mainly be recruited from three service organizations and thus around 35 from each organization in proportion to the total number of potential participants. Participants will be randomly assigned to receive Mindfulness-based Cognitive Therapy for Psychosis (MBCTp) plus TAU or TAU plus Psychoeducation for Psychosis (PEp). Simple randomization will be used to select subjects from the patient list in each organization to ensure that each participant will have equal opportunity to be included into the study (Altaman and Bland, 1999). A computer-based program (simple randomization) will be used to aid the randomization procedure. Assignment to the study groups will be made independently of staff involved in the recruitment and management of participants in the study. Raters who collect follow-up data will also be blind to the identity of participants. Considerable efforts will be made to ensure the blindness of raters such as storage of data will be kept separate from the therapists and raters who will be working in different rooms. All data will be locked in a cabinet with limited access only by responsible raters and recorded in a logbook.

Sample size
Sample size has been estimated on the basis of previous clinical trials of mindfulness interventions for people with psychosis, in which the primary outcome of depression and anxiety (effect size=0.76), and distress relating to psychotic symptoms (effect size=0.50) were the main outcomes (White et al., 2011; Chadwick et al., 2016). Study power calculation indicated that 82 participants (n=41 per group) were required to detect statistically significant differences on emotional distress between two groups with effect size of 0.63 at post-intervention, p=0.05 and power of 0.80 (Stevens, 2009). Taking account of a 15% attrition, the total sample size required should be 95 (n=48 per group).

Interventions
MBCTp will be delivered to the study groups while PEp will be delivered to the control groups. Intervention groups will be facilitated by the researcher who is experienced in cognitive therapy and mindfulness. The psychoeducation group will be conducted by a research assistant (RA1) who is an experienced psychiatric nurse and is trained by the researcher and an experienced psychoeducation researcher. All sessions will consist of 12-weekly 1.5- hour sessions, plus 12-week practice at home with guided CDs which comprises short mindfulness practice (Chadwick et al, 2016). Mindfulness practice will be with guided verbal instructions offered every couple of minutes to avoid prolonged silence. Mandatory individual home practice will be devised and completion of homework will also be assessed by counting the number of submissions and percentage of

completion per program. The session content will be protocoled according to the origins of MBSR (Kabat-Zinn, 2013) and MBCT (Teasdale, Williams and Mark, 2014) (Appendix 1). It will also be validated by a panel of experts including psychiatrists, clinical psychologists and psychiatric nurses who are experienced in mindfulness and cognitive therapy. Psychoeducation (psychosis) (PEp) will be developed based on the manuals produced by the Early Psychosis Prevention and Intervention of the Early Psychosis Prevention and Intervention Centre (EPPIC) National Support Program (ENSP), Australia and the psychoeducation manual produced by the Foundation for Life Sciences, University of Technology Sydney, Australia (Creek et al, 2015; Perry et al, 2012). It will be validated by a panel of experts and previewed by 5-10 service users in the pilot study.
To ensure treatment fidelity, three to four sessions will be randomly audio-recorded per intervention group to make up a full program for progress evaluation and commented by an experienced psychiatrist who has been practicing mindfulness and cognitive therapy for over 10 years based on the validated manualized protocol and the Mindfulness-Based Interventions Teaching Assessment Criteria (MBI:TAC) (Crane et al, 2013). The attendance and dropping-out of patients in both treatment and active control group will be continuously monitored by the researcher.

Outcome Evaluation
The primary outcome will be the Depression Anxiety Stress Scale- Short form (DASS-21) (Lovibond & Lovibond, 1995). It is chosen as the primary outcome measurement because scales of anxiety and depression possess the capacity to differentiate from the related state of tension and stress linking with environmental demands and emotional and physical disturbance. It is a 21-item instrument that measures over the past week symptoms of depression, anxiety and stress rated by 4-point severity or frequency scale. The scale is from 0 (did not apply to me at all) to 3 (applied to me very much or most of the time). Internal consistency for each scale for the DASS normative sample are as follows: Depression α=0.91; Anxiety α= 0.84; Stress α=0.90. The phi coefficients of the Chinese DASS-21 version are as follows: Beck Depression Inventory and Beck Anxiety Inventory are Depression-Anxiety 0.81; Anxiety-Stress 0.88 and Depression-Stress 0.83 (Moussa, Lovibond and Laube, 2001).

The secondary outcome measures will be including:
The Emotion Regulation Questionnaire (ERQ) (Gross and John, 2003) is a 10-item scale that was developed to measure participants' tendency to regulate their emotions in cognitive reappraisal and expressive suppression. Items are scored on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). The internal consistency reappraisal items are from α= 0.75 – 0.82 while suppression items are from α= 0.68 – 0.76. The reliability for reappraisal and suppression is α=0.79 and α=0.73 respectively.

The WHOQOL-100 (Li, Young, Xiao, Zhou and Zhou, 2004) which is a self-administered questionnaire consisting of 100 items and among them, there are six domains: physical, psychological, level of independence, social relationship and environmental and spirituality. The internal consistency is acceptable (α=0.76 – 0.90 across domains) and the validity is strong (α = 0.72 – 0.82) across all domains.

Positive and Negative Syndrome Scale (PANSS) (Kay, Fiszbein and Opler, 1987; Kay, Fiszbein and Opler, 2007) is a 30-item, 7-point scale measuring positive and negative syndrome, differentiation of clinical symptoms and severity of illness. The seven rating points represent increasing levels of psychopathology from 1 (absent) to 7 (extreme). The PANSS ratings will be derived from clinical interview, clinical reports or family members over the past one week. The overall alpha coefficients for the Positive and Negative Scales are 0.73 and 0.83 ($p<0.001$) respectively.

Acceptance and Action Scale (AAQII) (Bond et al., 2011). A seven-item questionnaire that is a commonly used self-report measure of experiential avoidance which also measures psychological inflexibility. The items are rated on a 7-point Likert scale from 1 (never true) to 7 (always true). Its internal consistency is α=0.78 - 0.88, while test-retest reliability is 0.81 and 0.79 for 3 and 12 months respectively. The internal consistency of a Chinese translated version for college students and athletes is ρ= 0.88 and ρ=0.85 respectively. The test-retest reliability is γ=0.86 and γ=0.74 across an average period of one month for college students and athletes (Zhang et al, 2014).

Five Facet Mindfulness Questionnaire (FFMQ) (Baer et al, 2006) is a 39-item self-report questionnaire that measures five facets of mindfulness: observing; describing; acting with awareness; non-judging and non-reacting. The internal consistency for each of the five facets are α=0.83, α=0.91, α=0.87, α=0.87 and α=0.75 accordingly. Items are scored on a 5-point Likert scale ranging from 1 (never or very rarely true) to 5 (very often or always true). The Chinese version of the Five Facet Mindfulness Questionnaire (FFMQ-C) obtained a good test-retest reliability (0.88) and a high internal consistency (0.83 in the community sample and 0.80 in the clinical sample) (Hou, Wong, Lo and Mak, 2013). A short form scale of the FFMQ (FFMQ-SF) is highly and significantly correlated with the FFMQ-C (r=0.96), and explained 91.3% of the variance of the FFMQ-C which will be adapted for the purposes of the study.

The last outcome assessment will be the number and length of re-hospitalization referenced from the case files and self-reporting.

Regarding the qualitative data obtained by focus group interviews, it will be used to determine the common themes being mentioned most frequently by participants and organized under different categories such as expectations, positive and negative outcomes, personal difficulties, positive and negative comments about the program and description.

Data collection procedure

There will be two research assistants (RA), RA1 will be responsible for conducting the psychoeducation program and RA2 will be blinded and doing data collection.
The RA2 will conduct the baseline measurements after obtaining the written consent and following comprehensive explanations about the study purpose and procedure and its ethical issues. After that, the participants will be assigned randomly to either study group or control group. Patients' outcomes at the ICCMWs will be measured at one week post-intervention using the same set of questionnaires as the baseline measures.

Two groups of 3-4 participants in treatment group will be interviewed in a quiet interview room in the ICCMWs, or as preferred by the participants. Participants with significant positive changes, minimal changes and negative changes will be invited according to the baseline and Post-test 1 measurement. Interviews in a focus group format will be conducted to identify the strengths and limitations and therapeutic components from the participants' perspective. Interview questions will be developed based on an open and broad basis criterion (Appendix 2). Audio-recorded group sessions will also be used to examine the group process/dynamics and participants' involvement and appraisals of the group program.

The outcome measurements will be completed by the participants at three and six months after the interventions with the help of RA1 who will be blind to the participants' assigned groups. By self-reporting or case files reviewing, re-hospitalizations of the participants will also be examined and calculated and checked against their medical records. Participants' recruitment, interventions, data (outcomes) collection, and data analyses are outlined in a flow diagram of Appendix 3, as recommended by the latest CONSORT statement.

Data Analysis

Intention-to-treat (ITT) analyses (Fisher et al, 1989) will be used to provide a more conservative estimate of outcomes. By using IBM SPSS, version 23.0, all data on participants' socio-demographic illness-related characteristics, attendance and completion rate, and study outcomes will be numerically coded, summarized and analyzed. Repeated-measures ANOVA tests will be used to assess any significant differences on all dependent (outcome) variables within and between groups and across three post-tests (one week, 3 months and 6 months follow-up).

Sub-group analysis for participants who will complete all sessions and those completers, and the outliers which can have deleterious effects on statistical analyses will also be screened. Defined completers will be those who have attended at least eight sessions by which the main themes of the program are covered (Nose, Barbui and Tansella, 2003).

Mediation analyses will be conducted to examine covariates of change in emotions and distress associated with psychotic symptoms by multiple regression analysis. Within – subjects effect sizes will also be reported based on Cohen's d statistic. Kaplan Meier survival analysis will be used for the analysis of re-hospitalization rates across treatment and control groups. The significance level of all statistical tests will be set at 5%. Clinical significance will be all subscales of DASS-21 shows a percentage improvement in mean scores in the range of approximately 45–55% pre- and post-intervention (Ng, Trauer, Dodd, Callaly, Campbell and Berk, 2007). For example, the mean DASS severity ratings of depression in pre-intervention is 31.2 and 16.2 in a week post-intervention. The difference is 15.0 and the percent change is 48.1 which is clinical significant. Reliable Change Index (RCI) will take into account the reliability of assessment instrument on scores of each participant between the pre-test and one post-test divided by the standard error of the difference between the two scores. Any value of RCI >1.96 (at $p<0.05$) will be considered statistically significant (Jacobson & Truax, 1991).

NVivo will be used to analyze the qualitative data on subjective experiences to mindfulness and acceptability to the interventions (Krippendorff, 2004). All audio-taped interviews will be transcribed into Cantonese/Chinese by the research assistant and checked for accuracy of transcription by the researcher. The revised transcripts

will be coded independently and important manifest and meanings in the data will be identified.

Ethical considerations

Approval for human subject research will be obtained from the three ICCMWs and Edinburgh Napier University before the start of data collection. The researcher will ensure and inform the potential participants that participation in the study is voluntary and that withdrawal from the study at any time will not affect any aspects of care. The information leaflet and consent form will be developed according to the format recommended by School of Health and Social Care ethics committee. All participants will be assured of the confidentiality of the data provided and the anonymity of their personal identity, and asked for permission to tape record the interviews and intervention sessions if selected. All data will be safely kept in a locked cabinet accessible only by the researcher.

Adverse events reporting and monitoring

All adverse events will be recorded according to criteria stipulated by the Research Ethics Committee of ICCMWs and Edinburgh Napier University. It may be including potential adverse events of meditational practices such as meditation related depersonalization, derealization and disturbing psychotic symptoms (Sharma, Gupta and Sagar, 2015), and feelings of intense anxiety and depression. A trained professional on the research team will be present to advise the participant and provide ad hoc psychological support. Each event will be examined by an independent panel which includes expert clinicians in the area of psychosis to minimize the risk of bias in the critique to whether the adverse event is interrelated or not to meditation. Furthermore, participants on trial with a PANSS 25% or more deterioration and demonstrating unexpected effects will be reported (Leucht et al, 2005).

Potential implications/significance of the study

Several small, non-randomised controlled studies have supported that mindfulness interventions for individuals with psychotic disorders specifically in treating negative symptoms is feasible and effective. This randomized controlled study will further confirm previous findings, test for generalization by using a standardized and validated intervention protocol and investigate potential moderators (e.g. attention regulation, acceptance, body awareness, cognitive appraisals) of mindfulness-based intervention in managing emotional dysregulation and symptoms.

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Appendix 1: Protocols for Mindfulness-based Cognitive Therapy for Psychosis (MBCTp) and Psychoeducation for Psychosis (PEp)

Session	MBCTp	PEp
1	Theme: Wake up from automatic pilot Activities: relationship building; orientation; establishment of ground rules; eating practice; 10- min body scan (thought, sensations and feelings); enquiry	Theme: Orientation Activities: relationship building; orientation; establishment of ground rules; program introduction; service information; enquiry
2	Theme Knowing in the awareness Activities: Doing mind exercise (thoughts are not facts);10- min body scan; 10- min sitting meditation; enquiry	Theme: Understanding psychosis I Activities: introduction; conceptualizations of psychosis; biopsychosocial factors in psychosis; enquiry
3	Theme: Living to the present Activities: pleasant experiences calendar; stretch and breath meditation; 10- min sitting with breath and body; enquiry	Theme: Understanding psychosis II Activities: the stress-vulnerability model; symptoms of psychosis; the phases model; enquiry
4	Theme: Gathering the wandering mind Activities: unpleasant experiences calendar; mindful stretching; 3-minute breathing space; enquiry	Theme: Understanding psychosis III Activities: understanding diagnosis; common myths about psychosis; co-occurring psychiatric conditions; enquiry
5	Theme: Looking out the aversion Activities: freeze-framing aversion; defining the territory of psychosis; 3-min breathing space; enquiry	Theme: Understanding psychosis IV Activities: psychosis in the acute, early, late and incomplete recovery; enquiry
6	Theme: Attending the experience but not thoughts Activities: 15- min sitting meditation with choice awareness; mindful walking; 3-min breathing space, enquiry	Theme: Understanding treatment I Activities: introduction; psychosocial interventions; enquiry
7	Theme: Allowing Activities: 15- min sitting meditation with difficulties (negative self schema); 3-min breathing space (response); enquiry	Theme: Understanding treatment II Activities: medical treatment; aims and benefits of a medication and its potential side effects; enquiry
8	Theme: Thoughts are not facts Activities: 10- min sitting with breaths, body, sounds and thoughts/feelings; alternative viewpoints exercise (positive self schema); 3-min breathing space	Theme: Medication adherence Activities: medication regimen and its benefits

	(response to thought); enquiry	
9	Theme: Responding thoughts Activities: early warning activity; 3-minute breathing space; my relapse signature activity; enquiry	Theme: Discontinuing medication Activities: pros and cons; risk of relapse; side-effects; physical health; enquiry
10	Theme: Kindness the healing Activities: mastery and pleasure activity; nourishing and depleting; 3-minute breathing space (regular and responsive); enquiry	Theme: Involuntary treatment Activities: information about and reason for involuntary treatment; legal rights; enquiry
11	Theme: Making a difference Activities: an action plan; 3- minute breathing space (regular); enquiry	Theme: Relapse prevention Activities: introduction; relapse prevention; early warning signs; enquiry
12	Theme: Practice momentum and ending Activities: 10- min body scan; review; personal reflections; plans for practice continuum; closing sitting	Theme: Developing a wellbeing plan Activities: sleep hygiene; managing stress; reducing substance use; keeping healthy; enquiry

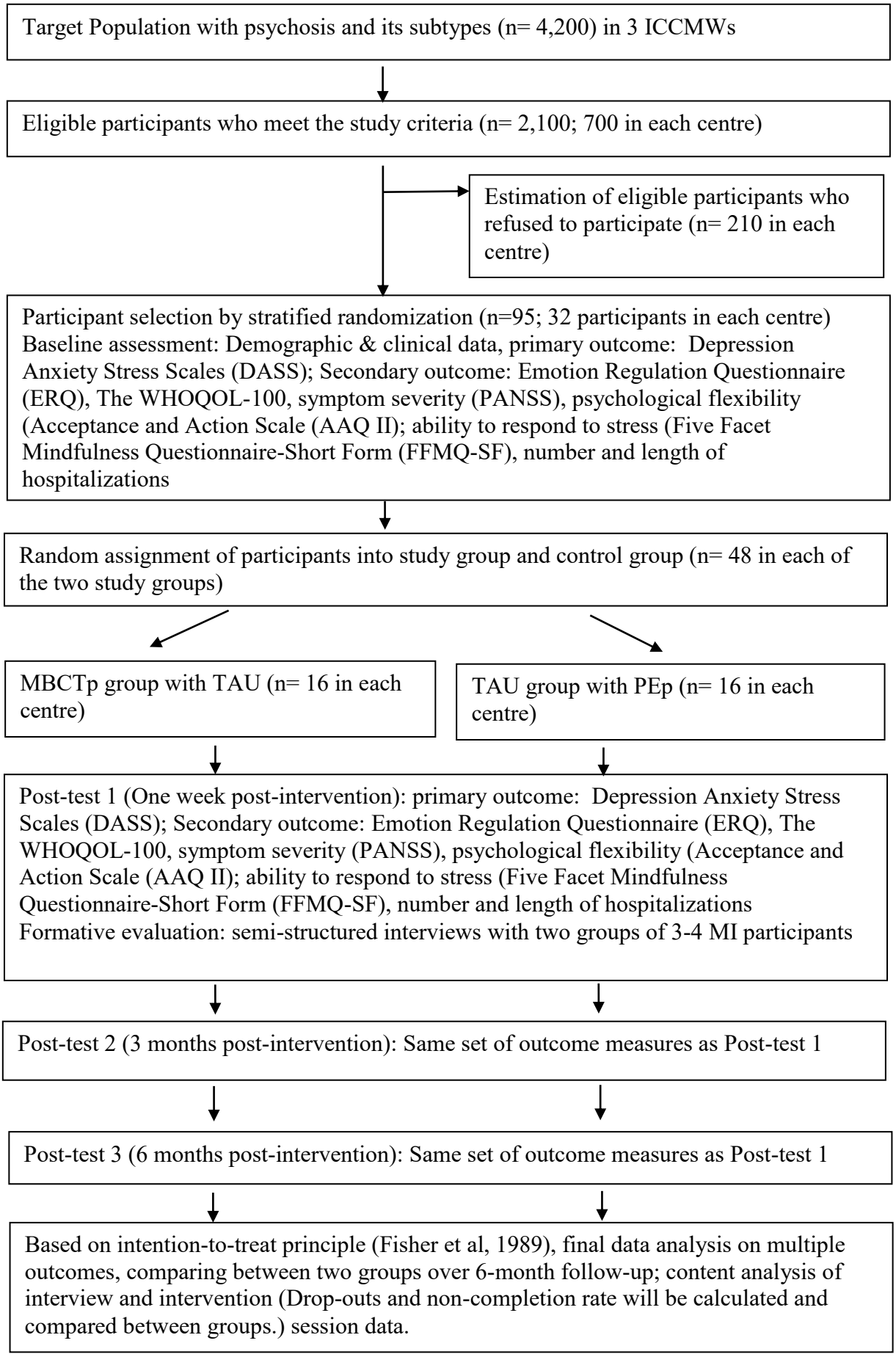
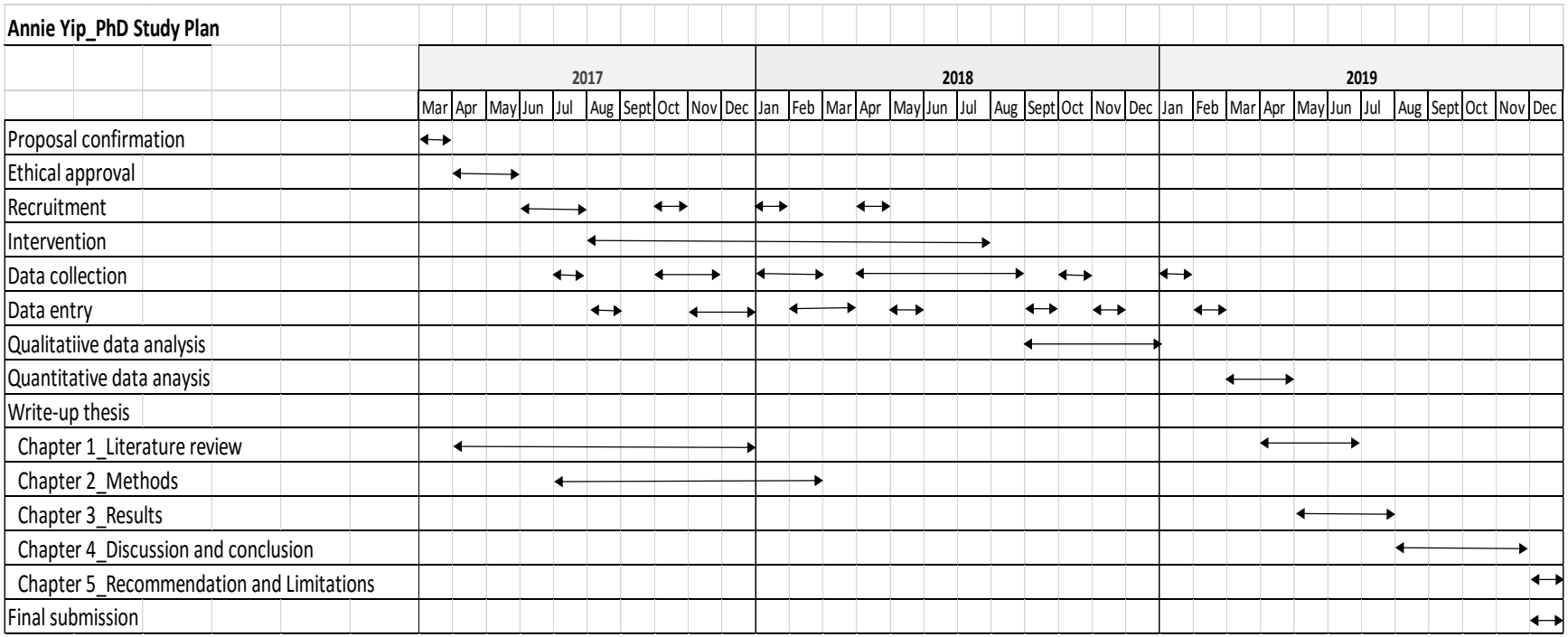
Appendix 2 Guidelines to Semi-structured Focus Group Interview

The interview may follow the questions as below:

We are interested in finding out about your experiences of the mindfulness program

	Interview Questions
1	What did you expect from the mindfulness program when you started?
2	Did the program reflect what you expected? How so? How not so?
3	How would you describe what the program is about and what you have learned?
4	What keeps you coming back to and finish the mindfulness program?
5	What do you particularly like about the mindfulness program?
6	What do you dislike or like less about the mindfulness program?
7	What is the most difficult and/or easy mindfulness activity?
8	What is it like using mindfulness? How would you describe mindfulness for you?
9	What have you found helpful or not so helpful about the mindfulness program?
10	How have you been feeling emotionally/physically/socially since the mindfulness program began? Any differences between now and before you joint the program?
11	What difficulties have you experienced in doing the homework?
12	Have you ever experienced any psychotic symptom? If yes, how did you respond to it?
13	In what way do you think that you have benefited from practicing mindfulness?
14	Did you find learning mindfulness in a group to be helpful?
15	What form might the mindfulness practice take place in the future?
16	How do you think people with psychosis should be best supported in community services?
17	What do you think could be done to improve the treatment program? Time, place, duration?
18	Is there anything you would like to mention and we have not covered in our discussion today?

Appendix 3 The CONSORT diagram of the Controlled Trial



Annie Yip_PhD Study Plan