A Proposal for an Evaluation Study of a Positive Psychotherapy Group Intervention of people with psychosis: A Randomized Controlled Trial.

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Introduction

The WELLFOCUS Positive Psychotherapy PPT, based on the hypothesis that it could improve people's wellbeing, was developed by Institute of Psychology and Neuroscience of King's college London, United Kingdom. It was originally developed for depression and is based on the premise that optimal treatment for depression involves directly and primarily building positive emotions, character strengths, and meaning rather than exclusively targeting negative symptoms, faulty cognitions and difficult relationships. PPT exercises focus on mindful savoring of enjoyable experiences, positive responding, identifying, developing and using character strengths, finding positives in negative events and also includes areas such as forgiveness and gratitude. It was adapted to use with people with psychosis. Preliminary evidence was shown to substantiate its effectiveness in improving people's positive wellbeing. (Schrank et al, 2015) The study was funded by Guy's and St. Thomas' Charity. There were significant changes shown from baseline to follow-up in the primary outcome measure, i.e. the wellbeing in the intervention group as shown by Warwick-Edinburgh Mental Well-Being Scale, WEMWBS, Positive Psychotherapy Inventory, PPI and Quality of Life, as well as other outcome measures, i.e. symptoms, depression, hope, self-esteem and sense of coherence. No significant change was found in the control group. In the between-group comparison, it found that there were significant improvements in wellbeing according to PPI and symptoms as well as depression. It was also found that WELLFOCUS PPT might be viable for reducing overall symptom severity and specifically depression for people with psychosis. A group of Occupational Therapists working in mental health service in Kwai Chung Hospital translated the WELLFOCUS Positive Psychotherapy PPT into Chinese with the permission granted by the original authors, Professor Mike Slade and Dr. Beate Schrank. 3-day training on using the programme and its theoretical base targeted for local clinicians was held in 11-13 January 2016 in Hong Kong by Dr. Schrank.

Aims of the study

The primary goal of conducting a Randomized Controlled Trial, RCT is to test whether an intervention works by comparing it to a control condition, usually either no intervention or an alternative intervention. With reference to the RCT conducted by Schrank (Shrank et al, 2015), we would plan a similar study in the Mental Health Service in Kwai Chung Hospital.

This study aims at evaluating the effectiveness of the WELLFOCUS Positive Psychotherapy Programme (Chinese version) used for people with psychosis in terms of their primary outcome in improving participants' wellbeing and other mental health outcomes. Hence, it helps to test the feasibility and applicability of the intervention adapted to improve the wellbeing of people with psychosis in local context of Hong Kong.

Methodology

The recruited subjects will be randomly allocated into either intervention group or control group. The intervention group will receive a 13-session of WELLFOCUS PPT with a group size of 8-10 in 7 consecutive weeks by trained therapists or co-therapists. The control group will receive treatment as usual (TAU).

Hypothesis:

WELLFOCUS is an effective intervention to improve the wellbeing and other mental health outcomes as compared to the control.

Intervention

WELLFOCUS Positive Psychotherapy PPT was manualized as an intervention, aiming to improve the wellbeing in people with psychosis by the research work from 2009-2015 by Prof. Mike Slade, Dr. Schrank Beate and their team. WELLFOCUS PPT is a strengths-based intervention, differing from many traditional therapies which tend to be deficit-based or problem-based. Hence, it includes exercises which look at identifying and developing personal strengths, noticing and remembering positive experiences, and topics such as gratitude and forgiveness. It also contains practical tools to aid understanding of the different topics, and to support maintenance of gains when the programme has finished. PPT exercises focus on mindful savoring of enjoyable experiences, positive responding, identifying, developing and using character strengths, finding positives in negative events and also includes areas such as forgiveness and gratitude. The final version of the manual contains 13 sessions covering,

1. Welcome to WELLFOCUS PPT
2. Positive experiences
3. Savoring
4. Good things
5. Identifying a personal strength
6. Personal strength activity
7. At my best
8. One door closes, another door opens
9. Forgiveness (1)
10. Forgiveness (2)
11. Gratitude
12. Looking back, moving forward
13. Celebration

Sessions would follow a generic structure: 90 minutes sessions, with 5 minutes savouring music at the beginning and end, and a 10 minute mid-session break with refreshments, to facilitate *engagement*. Emphasis on continuity between sessions leads to individual sessions beginning with a welcome, recap and warm-up exercise, to facilitate engagement, before introducing the main Ongoing Exercise. The more theory-laden content of standard

PPT has been shifted towards greater experiential tasks, with warm-ups and role-plays. The WELLFOCUS manual contains session-by-session guidance, example scripts, and therapist tips for all sessions. WELLFOCUS PPT uses additional supporting materials, including the WELLFOCUS Journal, session hand-outs, strengths pictures, Good Things Boxes, and WELLFOCUS PPT music. The journal includes pages for all sessions, which summarize the content, rationale, and Ongoing Exercise of each session.

Summary of WELLFOCUS PPT sessions

Session	Ongoing Exercise	Content	Target area(s)
1. Welcome to WELLFOCUS PPT	Positive Introduction	Group guidelines, rationale, positive responding	Positive experiences,· strengths
2. Positive Experiences	Positive responding	Positive responding, At my best	Positive experiences
3. Savouring	Planned savouring activity	Mindful eating, drinking and listening exercises	Positive experiences
4. Good Things	Identify good things	Identify recent good things using the Good Things Box	Positive experiences
5. Identifying a Personal Strength	Identify a character strength	Identify one character strength using strengths pictures	Strengths
6. Personal Strengths Activity	Strength Activity	Plan and carry out an activity using your strength	Strengths
7. At my best	Strength Activity with Significant Other	Plan and carry out activity that uses strengths of individuals	Strengths, positive relationships
8. One door closes, another door opens	One Door Closes Another Door Opens	Identify positive conclusions from negative experiences	Meaningful self-narrative
9. Forgiveness 1	A Sea of Forgiveness	Focus on letting go of a grudge	Positive relationships, meaningful self-narrative
10. Forgiveness 2	Forgiveness letter	Identify a person to forgive and write them a letter	Positive relationships, meaningful self-narrative
11. Gratitude	Writing a gratitude letter	Identifying a person you have never properly thanked and write them a letter	Positive relationships
12. Looking back, moving forward	Self review, positive experiences, Strengths	Personal Strengths, At my best, Group Discussion	Strengths, Positive relationships, meaningful self-narrative
13. Celebration	Positive responding	Celebrate achievements	Positive experiences

For details, please refer to the Chinese Intervention Manual of the WELLFOCUS Positive Psychology for Psychosis.

Measurements

All subjects, either intervention group or control group should sign on a written consent form (Appendix I) and be well informed of the aims of the research study. They will be measured with a baseline measurement, including basic demographic data and the following measurement tools which are commonly used in research studies in health field. After intervention, the whole series of outcome measures will be conducted again for both intervention group and control group.

Short Chinese Warwick-Edinburgh Mental Well-being Scale, C-SWEMWBS

Warwick-Edinburgh Mental Well-being Scale (WEMWBS) is a proven reliable and valid tool for assessing wellbeing of normal adults. A shortened 7-item version of WEMWBS with good internal construct and validity was derived in Hong Kong for people with mental illness in Hong Kong (Ng & et al, 2014). A 5-point Likert scale was used in the scale. Its internal consistency was reflected by 0.89 (Cronbach's alpha) which was consistent with the English version. The corrected item-total correlation was high. A single factor structure was similar to the original version by factor analysis. The scores of the C-SWEMWBS was positively correlated with the scores of the WHO5. The Short Chinese Warwick-Edinburgh Mental Well-being Scale showed high levels of internal consistency and reliability against accepted criteria. It is short, acceptable and culturally meaningful to clients with mental illness to measure their wellbeing.

Cantonese version of the Calgary Depression Rating Scale, CDSS-C

The scale was derived specifically to detect depressive symptoms in schizophrenic patients by a local psychiatrist. It is a nine-item scale with a 3-point Likert scale. The overall Cronbach's alpha was found to be 0.80 . The intra-class correlation coefficient for test-retest was 0.86. It showed significant correlations between the CDSS-C and Assessment of Positive Symptoms in delusion scale. Overall, the scale showed satisfactory reliability. It demonstrated concurrent validity. (Tsoi, 2003)

Brief Psychiatric Rating Scale, BPRS

The Brief Psychiatric Rating Scale (BPRS) is an 18-item observer-rated scale of psychiatric symptom severity (Overall & Gorham, 1988). It uses a seven-point Likert scale rated from 1 (not present) to 7 (extremely severe). The overall score is the sum of all items, ranging between 18 (low symptoms) and 126 (severe symptoms). The internal consistency of the overall scale lies between α=0.65 and 0.79, with sub-scales for withdrawal/retardation, thinking disorder, anxiety/depression, and activation vary between α=0.77 and 0.88. Inter-rater reliability for the BPRS has been reported between 0.87 and 0.97. In terms of clinical interpretation, a BPRS total score of 31 was found to correspond to a clinical global impression rating of 'mildly ill', 41 to 'moderately ill', and 53 to 'markedly ill'.

Hope Scale (Chinese Version)

It is a 12-item scale with a 8-point Likert scale to measure the perception of hope. It is composed items to measure the goal-directed determination and planning ways to meet goals. The internal consistency ranged from 0.74-0.84. The test-retest was 0.85. The factor analysis confirmed a two-factor structure. (Snyder, 1991).

The Chinese General Self-efficacy Scale (CGSS)

The Chinese General Self-efficacy Scale (CGSS) was derived locally in 2004. It consists of 10 items with a 4-point Likert scale. Its psychometric properties were tested with 78 individuals with psychosis. An excellent internal consistency (0.93) was found with very good to excellent test-re-test reliability (0.75-0.94). Exploratory factor analysis yielded a two-factor structure. The scale was considered as a reliable and valid tool to assess self-efficacy of Chinese with psychosis. (Chiu & Tsang, 2004)

SF-12 Health Survey

The SF-12 Health Survey is a common outcome measure in general quality of health of patients. It consists of 12 items. Its length and administration time within a few minutes makes it become widely used in clinical trials as compared to SF-36. The 12 items include two from each of physical functioning, role-physical, role-emotional, and mental health; and one item from general pain and general health. It was proven to be a valid tool to measure the health-related quality for the Chinese in Hong Kong. (Lam, 2005)

Health of the Nation Outcome Scales, HoNOS

HoNOS is a widely used 12-item scale to measure mental health outcome of social disability. Items cover a range of problem areas rated on a five-point scale between 0 (no problem) and 4 (serious problem) with a resulting overall score of up to 48. Cronbach's alpha for the scale varied between 0.59 and 0.76. The test-retest reliability was found to be mixed for HoNOS items, ranging between r=0.65 and 0.40 for seven items, and 0.31-0.32 for three items (Wing & et al, 1998, Brooks, R., 2000).

Summary of Outcome Measures

WELLFOCUS model component	Measure	Rater	Rationale
Distal Outcome			
Personal wellbeing	Short Chinese Warwick-Edinburgh Mental Well-being Scale, C-SWEMWBS #	Participants	Measures overall wellbeing
Proximal Outcome			
Symptom Relief	Cantonese version of the Calgary Depression Rating Scale, CDSS-C	Participants	Measures the reduction of depression
	BPRS	Researcher	Measures general symptom severity
Hope	Hope Scale- Chinese Version#	Participants	Measures Hope, indicator of wellbeing
Self-worth	The Chinese General Self-efficacy Scale, CGSS#	Participants	Measures self-worth, indicator of wellbeing
Other Outcomes			
QOL	SF-12 Health Survey#	Participants	QOL, a form of wellbeing measures
Social Disability	HoNOS	Researcher	Compares change in wellbeing with social disability

Chinese Version will be used.

Subjects

Inclusion Criteria:

- Aged 18-65 years old
- Primary diagnosis of psychosis (F20-29)
- Able to read written Chinese and speak Cantonese
- Willing to give written consent

Exclusion Criteria

- Cognitive impairment
- Active Substance abuse
- Unable to give consent

Sample Size Estimation

The sample size is estimated to detect difference of a medium effect size (0.5) on the primary outcome, i.e. the WEMWBS (type I error of 0.05 and power of 0.80) for the intervention group and the control group. To allow to detect the difference, 63 subjects should be recruited to each arm (total N=126). If 20% attrition is taken into consideration, 76 subjects in each arm and a total number of 152 should be recruited.

Power estimation is listed as follows when insufficient no. of subjects will be recruited: .

Hypothetical N @ arm	Power (1-β)
63	0.8
50	0.7
39	0.6

Recruitment and Randomization Procedure

In our plan, 10 series of the 13-session of WELLFOCUS PPT with a closed group size of 8-10 will be conducted in 7 consecutive weeks. All occupational therapists can refer potential and eligible service-users to the group. All referred service-users will be interviewed by a recruitment staff to explain the research to them, sign the written consent (Appendix I) with them and collect their basic demographic data. An identification number will be assigned to each potential participant. All subjects will be interviewed to collect the baseline measures as stated above. As a subsidy to their traveling expense to the baseline assessment, HK$100 will be given to the subjects who completes the baseline measure and later the outcome measure respectively, subject to the availability of funding resources by Health & Medical Research Fund. In addition to the consent form, all subjects will be given with an information card which indicates urgent enquiries about their participation to the study and urgent contact phone number. (Appendix III)

Allocation will be conducted using block randomization. When 16 potential participants have been recruited, they would be randomly allocated to either intervention group or control group. The randomization procedure will be conducted by their identification no.

Intervention Group & Control Group

The control group will receive treatment as usual, TAU under the care of occupational therapists. Subjects can receive standard care in the Occupational Therapy Department, such as prevocational training or interest group.

The Intervention Group will receive treatment as usual and in addition receive the WELLFOCUS PPT, a 13-session of WELLFOCUS PPT with a group size of 8-10 in 7 consecutive weeks by trained therapists and co-therapists.

Adverse effect and Risks

There was no adverse effect reported in the pilot trial in the King's College.

Outcome Measurements

The wellbeing is the primary outcome. The study aims to detect if there is any change in wellbeing in the subjects of the intervention group after going through the intervention as compared to the control group. The outcome measures will be the short version of the Warwick-Edinburgh Mental Wellbeing Scale, C-SWEMWBS. All other secondary outcomes, e.g symptoms, quality of life, and etc. will be measured by other five scales.

Quantitative Analysis

SPSS will be used to conduct the quantitative analysis in the trial. To ensure the homogeneity between the intervention group and control group prior to the intervention and to avoid possible confounders such as gender, age, no. of years of receiving mental health service, the baseline demographic data will be compared between two groups, i.e. gender by chi-square and t test for other continuous data. The baseline assessment on those outcome measures will be compared also by t test.

The outcome measures after the intervention will be compared with the baseline assessment. Paired t-test on each parameter will be run to see if there is any improvement within group. At follow-up, separate t test will be conducted to see if there is any significant difference between groups on each outcome parameter.

Intention-to-treat Analysis

Intention-to- treat, ITT analysis has become the "gold standard" for analyzing the results of clinical trials. (Armijo-Olivo et al, 2009) It is a strategy used to analyze the results of an RCT that considers the subjects in the way they were randomized at the beginning of the trial regardless of "lost to follow up", i.e. whether they completed the intervention given to their group or whether they withdrew from the treatment; or "Cross-over" i.e. what treatment they actually received. There are a number of approaches to handle the missing data when lost to follow up. The approach of dealing with the missing data in this RCT will be an endpoint analysis, i.e. "last observation carried forward, LOCF" which will include data for the last known state of the subjects in the analysis.

Fidelity to the Intervention

A 3-day training seminar was conducted by Dr. Beate Schrank in Hong Kong to train local clinicians to use the WELLFOCUS PPT in Jan 2016. Further sharing session will be arranged among trained therapists to ensure the implementation of each psychotherapy session prior to the research. Peer observation would be arranged to make sure the implementation will be based on the Chinese manual.

Therapists will conduct the WELLFOCUS according to the WELLFOCUS Positive Psychotherapy for psychosis Intervention Manual (Chinese) in which the sessional outlines, activities, scripts and materials of each session were well documented and defined. Dr. Beate Schrank will provide consultation after session via Skype to discuss and ensure the details of each session whenever necessary. Some sessions will be randomly recorded by videotape with written consent from subjects to record the therapist's implementation in the sessions. It would

be reviewed by the principal investigator and/or Dr. Schrank to comment on the fidelity. A third party personnel who is not the member in the research team will sit in randomly in some sessions to impartially check the implementation against the session contents of the Chinese manual in order to ensure the fidelity.

Timetable of the Study

Period	Duration (month)	Objectives	Target Tasks
Apr 2016 – Sep 2016	6	Application of Approval from REC Preparation for WELLFOUCS PPT Group	Sought approval All manuals and materials ready
Sep 2016	1	Introduction to the RCT	Seminar and briefing to all therapists concerning the protocol and subject recruitment
Oct 2016 – May 2018	20	Implementation of all series of PPT group	List of recruited subjects and randomized allocation to Intervention or Control Group Implementation of the Intervention
Jun 2018 – Sep 2018	4	Data Analysis and Report	Drafting the Preliminary report of the RCT

Data Handling, record keeping and publication

Both soft and hard data will be locked and kept for central storage like other patient information in the Main OT Department for at least 3 years. After storage for the aforesaid storage period, soft data will be permanently erased from storage and hard data, e.g. assessment forms and personal particulars form will be shattered.

Summary of statistical data without identifiable patients' particulars will be used to write up an article to be submitted to international journals, such as Psychiatric Service, Journal of Mental Health and /or Journal of Psychiatric Rehabilitation.

Declaration of Research Subject Protection

Our research team will try our best to conduct the trial in accordance with the standard in ICH-GCP (http://www.ich.org/home.html) as our study will involve the participation of human subjects. We will try our best to protect the rights, safety and wellbeing of our subjects in accordance to the principles stipulated in the Declaration of Helsinki. (http://www.wma.net/en/30publications/10policies/b3/index.html) The rights of our subjects will be put in the highest priority of concern to protect their health and rights with informed consent of our study to the subjects. As indicated in the consent, the subjects have their rights to quit the study without the need to provide any reason and their usual treatment will not be affected. The privacy of data will be protected. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned Research Ethics Committee before the study begins in order to ensure the ethical standard. We will amend our research protocol according to the advice by the Research Ethics Committee and ensure the implementation of the study in accordance with the ethical standard.

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Appendix I Consent Form

參與「正向心理治療小組成效研究」

同意書

甲部：研究簡介

「正向心理治療小組」乃倫敦國王學院一套改善個人心理健康的治療方法，葵涌醫院職業治療部為協助思覺失調患者，改善個人心理健康，希望引入及翻譯「正向心理治療小組」中文版。

「正向心理治療小組成效研究」將為其成效作有系統之對照研究。現誠意邀請　閣下參與此研究。參加此成效研究計劃費用全免。研究員將為　閣下進行第一次服務前有關心理健康的問卷評估，約四十五分鐘。成功完成問卷評估者將獲發港幣一百元車馬費。

其後將以隨機抽樣方式將　閣下分配到接受一般常行復康服務（共76人）或在常行復康服務之外接受為期十三節約七星期之「正向心理治療小組」（共 76 人)。完成治療小組後，研究員將為　閣下進行第二次有關心理健康的問卷評估，約四十五分鐘。成功完成第二次問卷評估者將獲發港幣一百元車馬費。

根據英國倫敦國王學院研究經驗及臨床應用，本「正向心理治療小組」不會對接受服務者有任何不良影響及危害。反之，「正向心理治療小組」實證可對一般心理健康及抑鬱症狀有一定的改善。

是次研究計劃所得之所有資料將會保密及只用於學術用途。當研究結果發表時，個人資料並不會被公開。

現誠邀　閣下參與此研究，允許研究員詢問　閣下之簡單個人資料及評估閣下之心理健康，並同意研究員查看閣下之醫療記錄。當簽妥參與研究同意書後，研究參加者及其合法代表授權予監測人、九龍西醫院聯網研究倫理委員及其他監管部門，可直接翻閱研究參加者的醫療紀錄正本，以查核研究進行的程序及／或資料，而不違反根據相關法律及指引所確保研究參加者個人資料保密之權利。如有需要，　閣下可先行與家人商討是否參與是次研究。你亦可隨時向研究員查詢任何與本研究有關之資料。參與此研究乃自願性質，參與與否，並不影響　閣下接受之其他治療服務。此外，　閣下可隨時通知研究人員退出此項研究而不需提供任何原因解釋。研究人員在有需要時按閣下利益著想，而终止　閣下參與研究。如有任何問題，參加者將按常行服務得到適切的照顧。

此研究已經通過醫院管理局九龍西聯網研究倫理委員會審閱及認可（查詢電話：2990 1017）。如有任何問題，請與研究員朱漢威先生(電話：6462 0243)聯絡。

乙部：參與研究同意書

本人已閱讀並明白上述研究簡介及由研究員(姓名) _____解釋此項研究之目的及內容。本人自願性質參與此研究，無論是否參與，將不影響本人恆常接受之精神科服務。本人明白本人可隨時通知研究人員退出此項研究而不需提供任何原因解釋。本人明白是次研究計劃所得之所有資料將會保密及只用於學術研究分析用途。當研究結果發表時，例如發表於科學期刊刊登或作醫療研討，任何可識別本人身份之個人資料並不會被公開。本人將獲取此簽妥之同意書副本作參考。

_____	_____	_____
病人簽署	病人姓名	日期
_____	_____	_____
研究人員簽署	研究人員姓名	日期

Appendix II Consent Form (As the funding resource is subject to the application of Health & Medical Research Fund, the following consent form will be given to the subjects if there is no monetary payment for the subjects.)

參與「正向心理治療小組成效研究」

同意書

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「正向心理治療小組」乃倫敦國王學院一套改善個人心理健康的治療方法，葵涌醫院職業治療部為協助思覺失調患者，改善個人心理健康，希望引入及翻譯「正向心理治療小組」中文版。

「正向心理治療小組成效研究」將為其成效作有系統之對照研究。現誠意邀請　閣下參與此研究。參加此成效研究計劃費用全免。研究員將為　閣下進行第一次服務前有關心理健康的問卷評估，約四十五分鐘。

其後將以隨機抽樣方式將　閣下分配到接受一般常行復康服務（共 76 人）或在常行復康服務之外接受為期十三節約七星期之「正向心理治療小組」（共 76 人）。完成治療小組後，研究員將為　閣下進行第二次有關心理健康的問卷評估，約四十五分鐘。

根據英國倫敦國王學院研究經驗及臨床應用，本「正向心理治療小組」不會對接受服務者有任何不良影響及危害。反之，「正向心理治療小組」實證可對一般心理健康及抑鬱症狀有一定的改善。

是次研究計劃所得之所有資料將會保密及只用於學術用途。當研究結果發表時，個人資料並不會被公開。

現誠邀　閣下參與此研究，允許研究員詢問　閣下之簡單個人資料及評估閣下之心理健康，並同意研究員查看閣下之醫療記錄。當簽妥參與研究同意書後，研究參加者及其合法代表授權予監測人、九龍西醫院聯網研究倫理委員及其他監管部門，可直接翻閱研究參加者的醫療紀錄正本，以查核研究進行的程序及／或資料，而不違反根據相關法律及指引所確保研究參加者個人資料保密之權利。如有需要，　閣下可先行與家人商討是否參與是次研究。你亦可隨時向研究員查詢任何與本研究有關之資料。參與此研究乃自願性質，參與與否，並不影響　閣下接受之其他治療服務。此外，　閣下可隨時通知研究人員退出此項研究而不需提供任何原因解釋。研究人員在有需要時按閣下利益著想，而终止　閣下參與研究。如有任何問題，參加者將按常行服務得到適切的照顧。

此研究已經通過醫院管理局九龍西聯網研究倫理委員會審閱及認可（查詢電話：2990 1017）。如有任何問題，請與研究員朱漢威先生(電話：6462 0243)聯絡。

乙部：參與研究同意書

本人已閱讀並明白上述研究簡介及由研究員(姓名) _____解釋此項研究之目的及內容。本人自願性質參與此研究，無論是否參與，將不影響本人恆常接受之精神科服務。本人明白本人可隨時通知研究人員退出此項研究而不需提供任何原因解釋。本人明白是次研究計劃所得之所有資料將會保密及只用於學術研究分析用途。當研究結果發表時，例如發表於科學期刊刊登或作醫療研討，任何可識別本人身份之個人資料並不會被公開。本人將獲取此簽妥之同意書副本作參考。

_____	_____	_____
病人簽署	病人姓名	日期
_____	_____	_____
研究人員簽署	研究人員姓名	日期

Appendix III Information Card for subjects for enquiries

參與「正向心理治療小組成效研究」聯絡卡

多謝閣下參與有關**「正向心理治療小組成效」**研究。

你可隨時向研究員查詢任何與本研究有關之資料。參與此研究乃自願性質，參與與否，並不影響　閣下接受之其他治療服務。此外，　閣下可隨時通知研究人員退出此項研究而不需提供任何原因解釋。研究人員在有需要時按閣下利益著想，而终止　閣下參與研究。

此研究已經通過醫院管理局九龍西聯網研究倫理委員會審閱及認可（ 查詢電話：2990 1017) 。如有任何問題，請與研究員朱漢威先生(電話：6462 0243)聯絡。