2017

Occupational therapy intervention development, for individuals with a diagnosis of psychosis living in the community, to improve participation in activities of everyday life: a feasibility study for a pragmatic randomised controlled trial.

Inman, Joanne

Appendix 1

UNIVERSITY of York
Centre for Reviews and Dissemination

NHS
National Institute for
Health Research

PROSPERO International prospective register of systematic reviews

Occupational therapy for people with a diagnosis of psychosis: a systematic review protocol

Joanne Inman, Katrina Bannigan, Jacqueline Akhurst

Citation

Joanne Inman, Katrina Bannigan, Jacqueline Akhurst. Occupational therapy for people with a diagnosis of psychosis: a systematic review protocol. PROSPERO 2015:CRD42015026706 Available from http://www.crd.york.ac.uk/PROSPERO_REBRANDING/display_record.asp?ID=CRD42015026706

Review question(s)

Does occupational therapy improve participation in activities of everyday life for adults with a diagnosis of psychosis?

Searches

The study selection process was piloted. Subsequently the following databases were searched individually; AMED; CINAHL; Cochrane Library; EMBASE, MEDLINE; OT Seeker and PsycINFO from 1990 up to July 2015. The reference lists of related systematic reviews will be scanned for potentially eligible studies. Key journals will be hand searched from 2005 to July 2015: American Journal of Occupational Therapy; Australian Journal of Occupational Therapy; British Journal of Occupational Therapy; Canadian Journal of Occupational Therapy; OTJR, occupation, participation and health, Occupational Therapy in Mental Health; Occupational Therapy International; Occupational Therapy Journal of Research; Scandinavian Journal of Occupational Therapy; Schizophrenia Bulletin and Schizophrenia Research.

The reference lists of all studies selected for inclusion will be scanned for potentially eligible studies. English language restrictions will be applied to the searches.

Link to search strategy

http://www.crd.york.ac.uk/PROSPEROFILES/26706_STRATEGY_20150829.pdf

Types of study to be included

Preliminary searches carried out whilst developing the systematic review protocol indicated limited effectiveness studies in this area, as previously identified (Bannigan and Spring 2012; Steultjens et al. 2005). Where there is a dearth of randomised studies it can become necessary to consider other designs (Khan et al. 2011). Steultjens et al. (2002) and Steultjens et al. (2004) addressed this issue by including efficacy studies which were either a randomised controlled trial (RCT) or a controlled clinical trial (CCT) or other design (OD), acknowledging that these designs can guide future research.

Subsequently the following types of study will be included (as described in Khan et al. 2011):

- Randomised controlled trial (with concealed allocation).

- Experimental study without randomisation (including quasi-experimental or quasi-randomised or pseudo-randomised studies).

- Observational study with control group; cohort study or case-control study.

- Observational study without control groups; cross-sectional study; before-and-after study and case series.

Condition or domain being studied

People with a diagnosis of psychosis and participation in activities of everyday life.

Participants/ population
Inclusion:

- Adults with a diagnosis of psychosis, including; schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder and affective psychosis e.g. bipolar disorder or unipolar psychotic depression (National Institute for Health and Care Excellence (NICE) 2014).

- Dual diagnosis where the diagnosis of psychosis is the primary diagnosis.

- Co-morbidity of physical ill health where the diagnosis of psychosis is the primary diagnosis.

- Identified occupational need and/ or Impairment and/or disability that indicated referral to occupational therapy; Steultjens et al. (2004) used impairment or disability that indicated referral to occupational therapy as eligibility criteria, in a systematic review of occupational therapy for community dwelling elderly people.

Exclusion:

- Children aged below 18 years old.

- People with non-psychotic mental health disorder as the primary diagnosis.

- People with dual diagnosis where the non-psychotic illness is the primary diagnosis.

- Co-morbidity of physical ill health where the physical health diagnosis is the primary diagnosis.

- People with a diagnosis of an organic brain disorder or suspected organic cause to the psychosis.

Intervention(s), exposure(s)
The intervention is occupational therapy; occupational therapy practice is focused on enabling individuals to change aspects of their person, the occupation, the environment, or some combination of these to enhance occupational participation (WFOT 2012).

Studies will be included when they investigate at least one of the following:

a. Occupational therapy practice as defined by WFOT (2012).

b. Occupational therapy designed to optimise participation in activities of everyday life.

Studies will be excluded when they primarily investigate:

a. Individual Placement Support (IPS).

b. Cognitive remediation.

c. Predictors of functioning/ recovery outcomes.

d. Cognitive behavioural therapy social skills/skills training not provided by an occupational therapist.

Comparator(s)/ control
Different types of interventions; usual care or no intervention for comparative studies or no comparator for observational studies without control groups, recommended as appropriate for the types of study designs in this systematic review (Khan et al. 2011).

Context
No limiters regarding context. Consideration of refinement was had about health care settings e.g. community, acute inpatients, residential rehabilitation or supported accommodation; however preliminary searches indicated limited effectiveness studies in this area and the context was unrefined to enable knowledge about effectiveness to be

reviewed in all contexts researched.

Outcome(s)

Primary outcomes

Participation in activities of everyday life is the primary outcome; studies must measure at least one of the primary or secondary outcomes (outlined below):

- Participation and satisfaction with activities of everyday life; both defined as outcomes of occupational therapy in the POSITION STATEMENT: Occupational therapy (2010) (WFOT 2012).

- Occupational performance in activities of daily living (includes self-care, productivity and leisure) is a core occupational therapy outcome (WFOT 2012) and sometimes referred to as functional ability (Bowling 2005).

- Time use in activities; this has been used as predictor of participation for people with a diagnosis of schizophrenia (Harvey et al. 2006).

There will be no limiters on the outcome measures used.

Secondary outcomes

Secondary outcomes are quality of life and health-related quality of life; participation and activities are part of the International Classification of Functioning, Disability and Health (ICF) (WHO, 2001) description of health and health related states and therefore this is anticipated to be a secondary outcome.

There will be no limiters on the outcome measures used.

Data extraction, (selection and coding)

Study selection

Two reviewers will carry out the citation screening independently by applying the pre-defined criteria for inclusion and exclusion to the titles and abstracts and full text when needed; full manuscripts of all citations considered relevant by either reviewer will be obtained (Khan et al. 2011). Two reviewers will independently examine the full texts of all the potentially relevant citations to see if the pre-defined criteria have been met or not; a list of excluded studies and the reason for exclusion will be recorded (Khan et al. 2011). Any disagreements will initially be resolved through discussion between the two reviewers and a third reviewer will be consulted for a decision where no consensus exists.

Data extraction

Data will be extracted by one reviewer and checked for completeness and accuracy by a second reviewer on a standardised form. The standardised form will be piloted before formal use in the review.

Risk of bias (quality) assessment

Risk of bias of included studies will be assessed by replicating the assessment process utilised by Steultjens et al (2002) in a systematic review of occupational therapy for rheumatoid arthritis. The quality assessment consists of 11 criteria for internal validity, six descriptive criteria and two statistical criteria. All criteria will be scored as yes, no or unclear. This list was initially recommended by Van Tulder et al (1997) and includes criteria proposed by Jadad et al (1996) and Verhagen et al (1998). RCT and CCT studies will be considered to be of high quality if at least six criteria for internal validity, three descriptive criteria, and one statistical criterion are scored positively.

The methodological quality of the ODs will also be assessed replicating the assessment process utilized by Steultjens et al (2002), who adapted a list created by Van Tulder et al (1997). The quality assessment consists of seven criteria for internal validity, four descriptive criteria, and two statistical criteria. All criteria will be scored as yes, no or unclear. Studies will be considered to be of sufficient quality if at least four criteria for internal validity, two descriptive criteria, and one statistical criterion are positively scored.

The risk of bias of all included studies will be assessed independently by two reviewers. Disagreements will be resolved by discussion and if no consensus is met a third reviewer will make the decision.

Strategy for data synthesis

Information from each of the studies will be tabulated including information about the populations, interventions, outcomes and effects found in each one of the studies and their confidence intervals (Khan et al. 2011). Meta-analysis of quantitative data will be completed if there is enough homogeneity between studies; however the preliminary searches indicated that this may not be possible. A Best-evidence synthesis will be used, as in the systematic review by Stueltjens et al. (2004), which was based on one proposed by Van Tulder et al. (2003). This attributes levels of evidence to the effectiveness of occupational therapy, taking into account the design of the studies, the methodological quality, type of outcome measures and the statistical significance of the findings. The Best-evidence synthesis also includes performing a sensitivity analysis by excluding low quality studies (Stueltjens et al. (2004).

Analysis of subgroups or subsets

Preliminary searches have indicated a focus of occupational therapy effectiveness research with this client group on skills training and vocational rehabilitation. Analysis of occupational therapy interventions will be applied to comprehensive occupational therapy i.e. occupational therapy practice that is focused on enabling individuals to change aspects of their person, the occupation, the environment, or some combination of these to enhance occupational participation (WFOT 2012). Further subgroup analysis will be considered for occupational therapy interventions that focus predominately on interventions in one of these three aspects.

Analysis of the clinical setting subgroups (community, hospital and residential rehabilitation/ supported accommodation) will be considered; however it is anticipated that the heterogeneity between the studies will prevent this from being valid analysis.

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Dissemination plans
The systematic review will be part of Joanne Inmans PhD thesis and it is aimed to be published in a peer reviewed journal and shared through conference presentations.

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Conflicts of interest
None known

Language
English

Country
England

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Humans; Occupational Therapy; Psychotic Disorders; Risk Factors

Stage of review
Ongoing

Date of registration in PROSPERO
30 September 2015

Date of publication of this revision
30 September 2015

Stage of review at time of this submission	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Appendix 2

Systematic review search strategies for all databases

Dates: From 1990- 31/07/15 2015

Databases	Search terms, Set 1 (Diagnosis/problem)	Boolean terms	Search terms, Set 2 (Intervention)
Medline CINAHL	"Psychotic disorders" (Major subject heading) OR "Schizophrenia" (Major subject heading) OR "Bipolar disorder" (Major subject heading)	AND	"Occupational therapy" (Major subject heading) OR "Vocational rehabilitation" (Major subject heading) OR "Self care" (Major subject heading) OR "Leisure activities" (Major subject heading) OR "Activities of daily living" (Major subject heading) OR "Skills training" (Title) OR "Life skills" (Title).
Psychinfo	"Psychotic disorders" (Major subject heading) OR "Schizophrenia" (Major subject heading) OR "Bipolar disorder" (Major subject heading)	AND	"Occupational therapy" (Major subject heading) OR "Vocational rehabilitation" (Major subject heading) OR "Self care skills" (Major subject heading) OR "Leisure time" (Major subject heading) OR "Activities of daily living" (Major subject heading) OR "Skills training" (Title) OR "Life skills" (Title).
AMED	"Psychotic disorders" (Subject) OR "Schizophrenia" (Subject)OR explode "Bipolar disorder" (Subject)	AND	Occupational therapy" (All fields) OR "Vocational rehabilitation" (Subject) OR "Self-care" (Subject) OR "Leisure activities" (Subject) OR "Activities of daily living" (Subject) OR "Skills training" (Title) OR "Life skills" (Title).
EMBASE	"Psychotic disorders" (Major subject heading) OR "Schizophrenia" (Major subject heading) OR "Bipolar disorder" (Major subject heading)	AND	"Occupational therapy" (Major subject heading) OR "Vocational rehabilitation" (Major subject heading) OR "Self-care" (Major subject heading) OR "Leisure " (Major subject heading) OR "Daily life activity" (Major subject heading) OR "Skills training" (Title) OR "Life skills" (Title).

Cochrane library	Psychosis (MeSH) OR Psychotic disorder (MeSH) OR Schizophrenia (MeSH)OR Bipolar affective disorder (MeSH)	AND	Occupational therapy (MeSH) OR Vocational rehabilitation (MeSH) OR Self care (MeSH) OR Leisure activity (MeSH) OR Activities of daily living (MeSH) OR "Skills training" (title) OR "Life skills" (title).
OTseeker	Schizophrenia (Diagnosis/ Subdiscipline) OR Affective disorders (Diagnosis/ Subdiscipline)	AND	"Basic activities of daily living" (Intervention) OR "Community living skills" (Intervention) OR "Instrumental activities of daily living" (Intervention) OR "Leisure/ recreation" (Intervention) OR "Purposeful activity" (Intervention) OR "Skill acquisition/ training" (Intervention) OR "Social skills" (Intervention) OR "Vocational retraining/ work" (Intervention).

Appendix 3

Systematic review inclusion and exclusion checklist

Study first author, date and title:

1a. Participants/ population, inclusion criteria	**Yes/ No or N/A**
- Adults with a diagnosis of psychosis, including; schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder and affective psychosis e.g. bipolar disorder or unipolar psychotic depression.	
- Identified occupational need and/ or Impairment and/or disability that indicated referral to occupational therapy.	
- Dual diagnosis where the diagnosis of psychosis is the primary diagnosis.	
- Co-morbidity of physical ill health where the diagnosis of psychosis is the primary diagnosis.	
1b. Participants/ population, exclusion criteria	**Yes/ No or N/A**
- Children aged below 18 years old.	
- People with non-psychotic mental health disorder as the primary diagnosis.	
- People with dual diagnosis where the non-psychotic illness is the primary diagnosis.	
- Co-morbidity of physical ill health where the physical health diagnosis is the primary diagnosis.	
- People with a diagnosis of an organic brain disorder or suspected organic cause to the psychosis.	

2. Interventions or exposures The intervention is occupational therapy; occupational therapy practice is focused on enabling individuals to change aspects of their person, the occupation, the environment, or some combination of these to enhance occupational participation (WFOT 2012). **Studies will be included when they fulfil 2a., b and c.**	**Yes/ No**
a. Occupational therapy practice was focused on enabling individuals to change aspects of their person, the occupation, the environment, or some combination of these to enhance occupational participation (WFOT 2012).	
b. Occupational therapy practice was primarily designed to optimise participation in activities of everyday life.	
c. Occupational therapy practice was predominately (over 75%) provided by a qualified occupational therapist or under the supervision of a qualified occupational therapist.	
3. Types of study; any one of the following designs will fulfil the eligibility criteria	**Yes/ No**
a. Randomised controlled trial (with concealed allocation).	
b. Experimental study without randomisation (including quasi-experimental or quasi-randomised or pseudo-randomised studies).	
c. Observational study with control group; cohort study or case-control study.	
d. Observational study without control groups; cross-sectional study; before-and-after study and case series.	
4. Outcomes; one or more of these outcomes will fulfil the eligibility criteria	**Yes/ No**
a. Participation and satisfaction with activities of everyday life.	
b. Occupational performance in activities of daily living (includes self-care, productivity and leisure).	
c. Functional ability.	
d. Time use in activities.	
e. Quality of life and/ or health-related quality of life.	
Decision made	**Eligible/ not eligible**

Appendix 4

Systematic review data extraction form

Research study reference

Characteristics of the study
Authors
No. of participants
Methods (RCT = randomised controlled trial, CTT = controlled clinical trial or OD = other design (*specify*)
Inclusion criteria/ setting
Experimental Intervention name
Theory Goal of intervention Procedures Materials Who provided Mode of delivery
Sessions Total number Intensity Frequency Duration Measurement of Fidelity and adherence
Control Intervention name
Theory Goal of intervention Procedures Materials Who provided Mode of delivery
Sessions Total number Intensity Frequency Duration Measurement of Fidelity and adherence
Outcomes and outcome measures

Effects of occupational therapy		
a. Participation and satisfaction with activities of everyday life.	**Mean (sd) baseline**	**SMD (95% CI)**
	I:	**I:**
	C:	**C:**
	Other (specify):	**Other** (specify):
b. Occupational performance in activities of daily living (includes self-care, productivity and leisure).	**Mean (sd) baseline**	**SMD (95% CI)**
	I:	**I:**
	C:	**C:**
	Other (specify):	**Other** (specify):
c. Functional ability.	**Mean (sd) baseline**	**SMD (95% CI)**
	I:	**I:**
	C:	**C:**
	Other (specify):	**Other** (specify):
d. Time use in activities.	**Mean (sd) baseline**	**SMD (95% CI)**
	I:	**I:**
	C:	**C:**
	Other (specify):	**Other** (specify):
e. Quality of life and/ or health-related quality of life.	**Mean (sd) baseline**	**SMD (95% CI)**
	I:	**I:**
	C:	**C:**
	Other (specify):	**Other** (specify):
Effects of occupational therapy		
Other (specify?)	**Mean (sd) baseline**	**SMD (95% CI)**
	I:	**I:**
	C:	**C:**
	Other (specify):	**Other** (specify):
Effects of occupational therapy		
Other (specify?)	**Mean (sd) baseline**	**SMD (95% CI)**
	I:	**I:**
	C:	**C:**
	Other (specify):	**Other** (specify):

Appendix 5

Criteria for methodological quality assessment (randomised controlled trials RCTs and controlled clinical trials CCTs

Study reference:

Methodological quality (Adapted and reproduced with permission granted from Steultjens et al 2002)			
Patient selection			**Notes**
a.	Were the eligibility criteria specified? *i.e. explicit diagnosis of psychosis including; schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder & affective disorder. AND Identified occupational need and/or impairment and/ or disability that indicated referral to occupational therapy.*		
b.	Treatment allocation:		
	1) Was a method of randomisation performed?		
	2) Was the treatment allocation concealed?		
c.	Were the groups similar at baseline regarding the most important prognostic indicators? *i.e. age, duration of illness and baseline outcome measures relevant to this review.*		
Interventions			**Notes**
d.	Were the index and control interventions explicitly described?		
e.	Was the care provider blinded for the intervention?		
f.	Were co-interventions avoided or comparable?		
g.	Was the compliance acceptable in all groups?		
h.	Was the patient blinded to the intervention?		
Outcome measurement			**Notes**
i.	Was the outcome assessor blinded to the		

	interventions?		
j.	Were the outcome measures relevant? At least one of the important outcome parameters i.e. *- participation in activities of everyday life* *- participation and satisfaction with activities of everyday life* *- occupational performance in activities of daily living* *- functional ability* *- time use in activities* *- quality of life and/or health related quality of life*		
k.	Were adverse effects described?		
l.	Was the withdrawal/ drop-out rate described and acceptable?		
m.	Timing follow up measurements:		
	1) Was a short-term follow up measurement performed? 2) Was a long-term follow up performed?		
n.	Was the timing of the outcome assessment in both groups comparable?		
Statistics			**Notes**
o.	Was the sample size for each group described?		
p.	Did the analysis include an intent-to-treat analysis?		
q.	Were point estimates and measures of variability presented for the primary outcome measures?		
		Total	
Notes	**Internal validity= b1, b2,e,f,g,h,i,j,l,n,p**		
	Descriptive criteria= a,c,d,k,m1, m2		
	Statistical criteria= o,q		
	High quality = six criteria internal validity, three descriptive criteria and one statistical criterion.	**Outcome**	

Appendix 6

Methodological quality assessment 'other designs' (ODs)

Research study reference:

Methodological quality (Adapted and reproduced with permission granted from Steultjens et al 2002)			
Patient selection			**Notes**
a.	Were the eligibility criteria specified? *i.e. explicit diagnosis of psychosis including; schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder & affective disorder. AND* *Identified occupational need and/or impairment and/ or disability that indicated referral to occupational therapy.*		
Interventions			**Notes**
d.	Was the intervention explicitly described?		
f.	Were co-interventions avoided?		
g.	Was the compliance acceptable?		
Outcome measurement			**Notes**
i.	Was the outcome assessor not involved in the treatment?		
j.	Were the outcome measures relevant? i.e. *- participation in activities of everyday life* *- participation and satisfaction with activities of everyday life* *- occupational performance in activities of daily living* *- functional ability* *- time use in activities* *- quality of life and/or health related quality of life*		
k.	Were adverse effects described?		
l.	Was the withdrawal/ drop-out rate described and acceptable?		
m.	Timing follow up measurements:		
	3) Was a short-term follow up measurement		

	performed? 4) Was a long-term follow up performed?		
n.	Was the timing of the outcome assessment in all participants comparable?		
Statistics			**Notes**
o.	Was the sample size of the patient group described?		
p.	Did the analysis include an intent-to-treat analysis?		
q.	Were point estimates and measures of variability presented for the primary outcome measures?		
		Total	
Notes	**Internal validity=,f,g,i,j,l,n,p**		
	Descriptive criteria= a,d,k,m1, m2		
	Statistical criteria= o,q		
	Sufficient quality = four criteria internal validity, two descriptive criteria and one statistical criterion met.	**Outcome**	

Appendix 7

FAST-R Service Feedback

NHS National Institute for Health Research

Clinical Research Network
Mental health

Study Title: The POINTER study

Submitted by: Joanne Inman
Investigator: Joanne Inman

Date Received: 07-08-2014
Date Reviewed: 13-08-2014

The reviewers found this study very interesting and were encouraged by the potential of this area of research. The reviewers stated they would be pleased to review later editions should this be helpful.

General feedback and observations:

- Please find the majority of the feedback included as track changes on the submitted protocol. Given that the two information sheets are very similar, track changes have generally been made to the participant information sheet, but equally apply to that of the therapist information sheet unless otherwise stated.
- Overall the reviewers felt that the information sheet very good. They did pick up on a number of sections which could be expanded to ensure participants are better informed, however. Due to the length of the information sheet, this may mean other sections needing revision as it is already a fairly lengthly document.
- The reviewers felt there could be a scope for carer involvement in the study to be expanded somewhat. They also considered a PPI plan for continued involvement in the study to be important.
- The group felt the inclusion/exclusion criteria to be quite wide and requiring further definition. For example, the minimum age of 18 is stated but no upper age range. Also how early intervention status will be classified requires clarification.
- The reviewers wondered whether previous experience of occupational therapy (or not) could affect participation in this study.
- The reviewers also questioned whether there will be collaboration with the rest of the individual participant's care team.

Many thanks for using FAST R Service. We hope you have found it useful and please do let us know if you need any more support or feedback.

The CRN: Mental Health is funded by and part of the National Institute for Health Research, and is one of the Topic Specific Networks of the NIHR Clinical Research Network

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Appendix 8

FAST-R Service Feedback

NHS National Institute for Health Research

Clinical Research Network
Mental health

Study Title: The effectiveness of occupational therapy at enabling people with a diagnosis of psychosis, living in the community, to improve participation in their activities of everyday life.

Investigator: Joanne Inman

Date Received: 01-09-2014

Date Reviewed: 04-09-2014

The reviewers found the study premise very interesting and agreed that this is a very worthwhile piece of work.

General comments:

- Please find the majority of the feedback included as track changes on the submitted participant and occupational therapist (OT) Information Sheets.
- The reviewer felt the comments from the previous review have been addressed in these updated documents and provided additional comments.
- Overall the information sheet was well written and easily understandable.
- Regarding the feasibility of recruitment, the reviewer felt it would have been useful to know how many OT's need to be recruited for an adequate sample and will they be recruited from one centre or many?
- It was felt that financial incentive and payment of expenses may aid recruitment if this is not to be offered already.
- Lots of questions arose around how the focus group will work. It was felt that this needed clarification in the information sheet.

Many thanks for using FAST R Service. We hope you have found it useful and please do let us know if you need any more support or feedback.

The CRN: Mental Health is funded by and part of the National Institute for Health Research, and is one of the Topic Specific Networks of the NIHR Clinical Research Network

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Appendix 9

FAST-R Service Feedback

NHS National Institute for Health Research

Clinical Research Network
Mental health

Study Title: The effectiveness of occupational therapy at enabling people with a diagnosis of psychosis, living in the community, to improve participation in their activities of everyday life.

Investigator: Joanne Inman

Date Received: 02-09-2014

Date Reviewed: 15-09-2014

The reviewers found the study premise very interesting and agreed that this is a very worthwhile piece of work.

General comments:

- Please find the majority of the feedback included as track changes on the submitted questionnaire and conversation guide.
- With regards to the questionnaire the reviewers felt the questions could be simplified and provided examples. They felt the rating scale did not make sense in view of the phrasing of the questions and provided an alternative scale. They felt some words such as 'adherence',' enablers' and 'barriers' could be avoided.
- Reviewers noted that the conversation guide would be key in standardising any focus groups taking place. They felt emphasise should be placed on this being a guide and that the facilitator should aim to relate the questions to the focus group members to maximise engagement.
- Reviewers appreciated the fact that this work encompasses improving quality of life measures. They felt it is a key part of recovery and good activity in building the evidence base.

Many thanks for using FAST R Service. We hope you have found it useful and please do let us know if you need any more support or feedback.

The CRN: Mental Health is funded by and part of the National Institute for Health Research, and is one of the Topic Specific Networks of the NIHR Clinical Research Network

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Appendix 10

Health Research Authority
National Research Ethics Service

NRES Committee North West - Lancaster
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7109
Fax: 0161 625 7919

03 December 2014

Ms Joanne Inman
North Barn, Pathfinder Drive
Lancaster
LA1 3JT

Dear Ms Inman

Study title:	**The effectiveness of occupational therapy in enabling people with a diagnosis of psychosis, living in the community, to improve participation in their activities of everyday life.**
REC reference:	**14/NW/1426**
Protocol number:	**N/A**
IRAS project ID:	**136946**

Thank you for your letter of , responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Mrs Carol Ebenezer, nrescommittee.northwest-lancaster@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper [IRAS application covering letter]	1	30 October 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Employers liability insurance, Plymouth University]		01 August 2014
GP/consultant information sheets or letters [POINTER Study Consultant Psychiatrist/ Staff Information Sheet]	2	23 November 2014
GP/consultant information sheets or letters [POINTER Study Consultant Psychiatrist Letter]	1	23 November 2014
Interview schedules or topic guides for participants [POINTER Study Occupational Therapists Focus Group]	2	07 October 2014
Letter from statistician [Statistical review, Professor John Marsden]	1	12 September 2014
Letters of invitation to participant [POINTER Study Participant	1	08 October 2014

Invitation Letter]		
Non-validated questionnaire [POINTER Study Participant Questionnaire]	2	07 October 2014
Other [Professional negligence insurance, Plymouth]	1	13 June 2014
Other [CV, Collaborator LCFT, Sally Underwood]	1	07 October 2014
Other [CV, Collaborator, TEWV, Alison Bullock]	1	04 October 2014
Other [POINTER Participant Registration Form]	1	08 October 2014
Other [POINTER Study Occupational Therapist Registration Form]	1	05 September 2014
Participant consent form [POINTER Study Occupational Therapist Consent Form]	4	23 November 2014
Participant consent form [POINTER Study Occupational Therapists Focus Group, Consent Form]	1	23 November 2014
Participant information sheet (PIS) [POINTER Study Participant Information Sheet]	4	23 November 2014
Participant information sheet (PIS) [POINTER Study Occupational Therapist Information Sheet]	4	23 November 2014
REC Application Form [REC_Form_04112014]		04 November 2014
Research protocol or project proposal [POINTER Study Protocol]	2	31 August 2014
Research protocol or project proposal [POINTER Study Protocol]	3	28 December 2014
Summary CV for Chief Investigator (CI) [CV Chief investigator & PhD Student, Joanne Inman]	1	07 October 2014
Summary CV for student [Cv, Chief Investigator & PhD Student]	1	07 October 2014
Summary CV for supervisor (student research) [CV Supervisor, Dr Katrina Bannigan]	1	04 October 2014
Summary CV for supervisor (student research) [Professor J Akhurst]		
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Occupational Therapy Pathway]	5	31 August 2014
Summary, synopsis or diagram (flowchart) of protocol in non technical language [POINTER Study Enrolment Process]	6	28 November 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

14/NW/1426	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

pp

Dr Lisa Booth
Chair

Email:nrescommittee.northwest-lancaster@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Professor Graham Sewell*
Mrs Beverley Lowe, Lancashire Care NHS Foundation Trust

Appendix 11

Lancashire Care NHS
NHS Foundation Trust

Lancashire Care NHS Foundation Trust
Research and Development
The Lantern Centre
Vicarage Lane
Fulwood
Preston
PR2 8DW

Tel: 01772 773498
Research@lancashirecare.nhs.uk

16th December 2014

Ms Joanne Inman
Occupational Therapy Professional Lead & PhD Student
Lancashire Care NHS Foundation Trust
North Barn
Pathfinder Drive
Lancaster
LA1 3JT

Dear *Ms Inman*,

Re: NHS Trust Permission to Proceed

Project Reference: 14/29

Project Title: *The effectiveness of occupational therapy in enabling people with a diagnosis of psychosis, living in the community, to improve participation in their activities of everyday life*

I am pleased to inform you that the above project has received research governance permission.

Please take the time to read through this letter carefully and contact me if you would like any further information. You will need this letter as proof of your permission.

Trust R&D permission covers all locations within the Trust; however you will only be allowed to recruit from the sites/services you have indicated in section 3 of the SSI application form. If you would like to expand recruitment into other services in the Trust that are not on the original SSI then you must contact the R&D department immediately to discuss this before doing so.

You also must ensure you have liaised with and obtained the agreement of individual service/ward managers before commencing recruitment in that service and you must contact the relevant service/ward managers prior to accessing the service to make an appointment to visit before you can commence your study in the trust.

Please make sure that you take your Trust permission letter with you when accessing Trust premises and please include the Trust reference number on any correspondence/emails so that the services are assured permission has been granted.

Honorary Research contracts (HRC)
All researchers with no contractual relationship with any NHS body, who are to interact with individuals in a way that **directly affects the quality of their care**, should hold Honorary Research NHS contracts. Researchers have a contractual relationship with an NHS body either when they are employees or when they are contracted to provide NHS services, for example as independent practitioners or when they are employed by an independent practitioner (*Research Governance Framework for Health and Social Care,* 2005). If a researcher does not require an HRC, they would require a Letter of Access (LoA). For more information on whether you or any of your research team will require an HRC or LoA please liaise with this office. It is your responsibility to inform us if any of your team do not hold Honorary Research NHS contracts/Letters of Access.

Staff involved in research in NHS organisations may frequently change during the course of a research project. Any changes to the research team or any changes in the circumstances of researchers that may have an impact on their suitability to conduct research MUST be notified to the Trust immediately by the Principal Investigator (or nominated person) so that the necessary arrangements can be put in place

Research Governance
The Research Governance Sponsor for this study is Plymouth University. Whilst conducting this study you must fully comply with the Research Governance Framework. This can be accessed at: http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4108962&chk=Wde1Tv
For further information or guidance concerning your responsibilities, please contact your research governance sponsor or your local R&D office.

Good Clinical Practice (GCP)
GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. It is the responsibility of all researchers who are carrying out a research project involving NHS patients and carers to complete GCP training and to update this every 2 years. All training certificates must be forwarded to the R&D department to comply with Trust permission. Please note that student projects are exempt from this process.

Risk and Incident Reporting
Much effort goes into designing and planning high quality research which reduces risk; however untoward incidents or unexpected events (i.e. not noted in the protocol) may occur in any research project. Where these events take place on trust premises, or involve trust service users, carers or staff, you must report the incident within 48 hours via the Trust incident reporting system. If you are in any doubt whatsoever whether an incident should be reported, please contact us for support and guidance.

Regardless of who your employer is when undertaking the research within Lancashire Care NHS Foundation Trust you must adhere to trust policies and procedures at all times.

Confidentiality and Information Governance
All personnel working on this project are bound by a duty of confidentiality. All material accessed in the trust must be treated in accordance with the Data Protection Act (1998) For good practice guidance on information governance contact us.

Protocol / Substantial Amendments
You must ensure that the approved protocol is followed at all times. Should you need to amend the protocol, please follow the Research Ethics Committee procedures and inform all NHS organisations participating in your research.

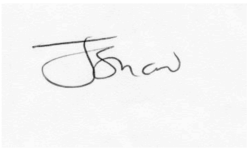
Monitoring / Participant Recruitment Details
If your study duration is less than one year, you will be required to complete an end of study feedback report on completion. However if your study duration is more than one year, you will be required to complete a short electronic progress report annually and an end of study report on completion. As part of this requirement, please ensure that you are able to supply an accurate breakdown of research participant numbers for this trust (recruitment target, actual numbers recruited). To reduce bureaucracy, progress reporting is kept to a minimum; however, if you fail to supply the information requested, the trust may withdraw permission.

Recruitment
Please provide the trust details of your recruitment numbers when requested. If you have any concerns with recruitment please contact the R&D team immediately for assistance.

Final Reports
At the end of your research study, we will request a final summary report so that your findings are made available to local NHS staff. The details from this report may be published on the NHS Trust internet site to ensure findings are disseminated as widely as possible to stakeholders. You may also be invited to present your findings to the Trust at an event or meeting.

On behalf of this Trust, may I wish you every success with your research. Please do not hesitate to contact us for further information or guidance.

Yours sincerely,



Professor Jenny Shaw
R&D Director
On Behalf of the Research Governance Sub-Committee

Cc: Sally.Underwood@lancashirecare.nhs.uk
Gjsewell@Plymouth.ac.uk

Appendix 12

Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

Research & Development Office
Flatts Lane Centre
Flatts Lane
Normanby
Middlesbrough
TS6 0SZ
jackiemitchell2@nhs.net

22 December 2014

Ms Joanne Inman
Occupational Therapy Professional Lead & PhD Student
Lancashire Care NHS Foundation Trust

Dear Ms Inman

Title: **The effectiveness of occupational therapy in enabling people with a diagnosis of psychosis, living in the community, to improve participation in their activities of everyday life**
REC: **14/NW/1426**
R&D Ref: **0352/14**

I am pleased to inform you that you have successfully gained research governance approval from the TEWV NHS Foundation Trust to conduct this study. All local checks are met and we have received a favourable ethical opinion.

This research must be conducted in accordance with Tees, Esk and Wear Valleys NHS Foundation Trust policies and procedures, which are available to you on request. We require a report within three months of completion of the project outlining key findings for dissemination to clinicians, service users and carers as appropriate. We also encourage you to inform us of any publications which result from the project.

You must inform the R&D Office of any significant events or amendments in the course of the study, including:

- Early termination of the study, or continuation beyond the stated end date
- Significant adverse events
- Significant amendments to the study protocol

The Trust R&D Office conducts a yearly audit of research governance compliance, and you will be informed in advance if this study is due to be audited.

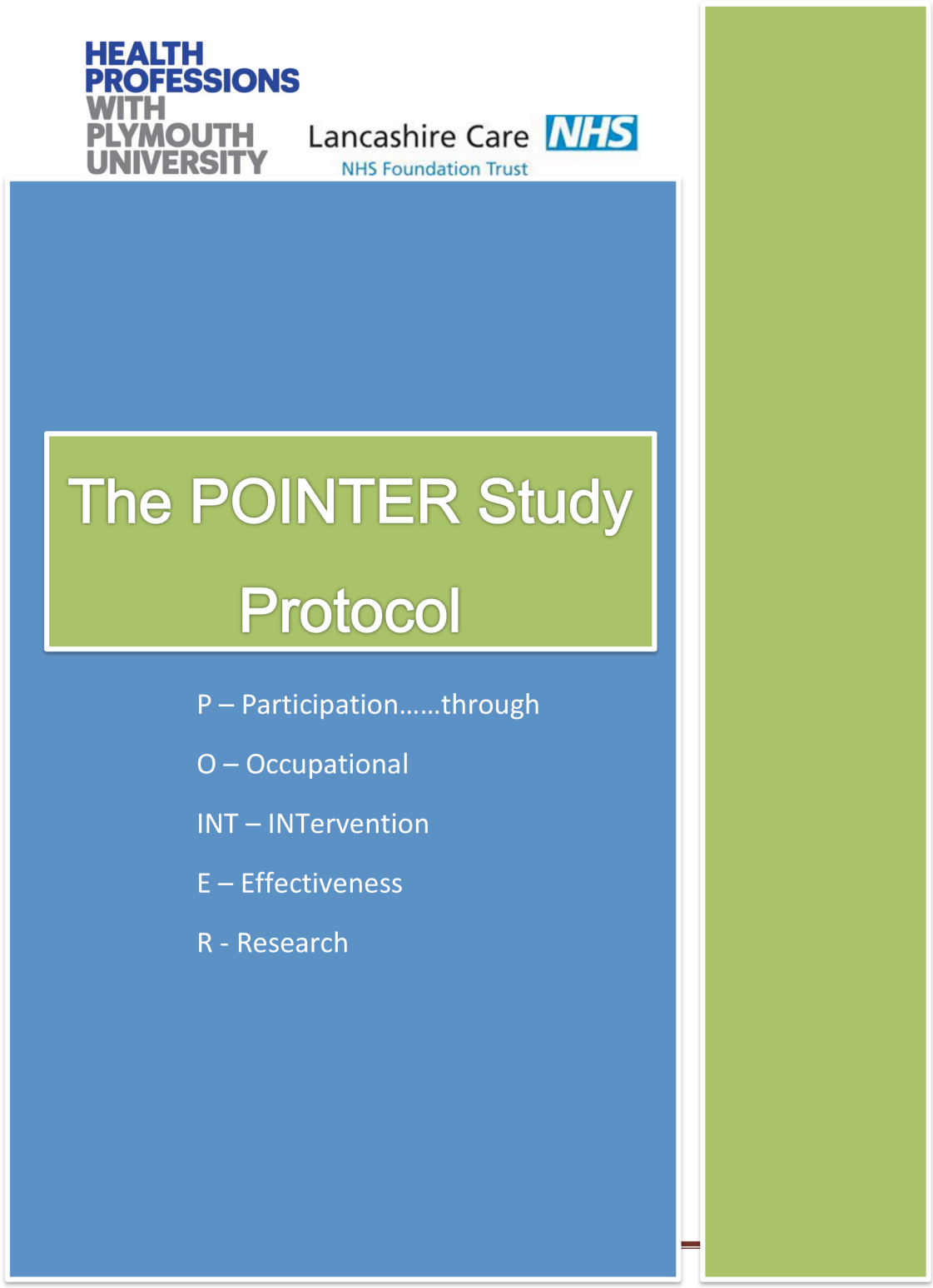
I would like to take this opportunity to wish you every success with your research. If there is any way that we can assist you in the future please contact us.

Yours sincerely

Jackie Mitchell
R&D Manager (Acting)

Cc: Alison Bullock, TEWV NHS FT

Appendix 13


HEALTH PROFESSIONS WITH PLYMOUTH UNIVERSITY
Lancashire Care NHS
NHS Foundation Trust
The POINTER Study Protocol
P – Participation……through
O – Occupational
INT – INTervention
E – Effectiveness
R - Research

The POINTER Study

Supported by:

York St John Studentship and currently by Plymouth University PhD Studentship

And

Lancashire Care NHS Foundation Trust

In collaboration with Tees, Esk and Wear Valleys NHS Foundation Trust

1.0 ACKNOWLEDGEMENTS:
Thank you to the following people for their contribution to the development of this protocol; Dr Katrina Bannigan, Associate Professor (Reader) of Occupational Therapy, Plymouth University; Professor Jacqui Akhurst, Community Psychology, York St John University; Alison Bullock, Trust Wide Professional Head of Occupational Therapy, Tees, Esk & Wear Valleys NHS Foundation Trust; Researching Occupation Participation Effectiveness (ROPE) Group; Ingrid Sturkenboon, Researcher, Medical Anthropologist & Occupational Therapist, Radboud University Medical Centre, The Netherlands; Professor Max Marshall, Medical Director, Lancashire Care NHS Foundation Trust; Dr Graeme Reid, Consultant Clinical Psychologist, Lancashire Care NHS Foundation Trust; Dr Carolyn Dunford, Head of Research, The Children's Trust; Mike Fitzsimmons, Clinical Lead, Early Intervention Services, Lancashire Care NHS Foundation Trust; Michelle Greatorex, Research Administrator, Lancashire Care NHS Foundation Trust; Occupational Therapy Clinical Colleagues at Lancashire Care NHS Foundation Trust and students and staff who attended the research seminar at York St John University.

1.1 CHIEF INVESTIGATOR: Joanne Inman, Occupational Therapy Professional Lead, Lancashire Care NHS Foundation Trust & PhD Student, Plymouth University.
North Barn, Pathfinder Dive, Lancaster, LA1 3JT

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1.2 ACADEMIC SUPERVISORS:
Dr Katrina Bannigan, Associate Professor (Reader) of Occupational Therapy. Plymouth University, Faculty of Health and Human Sciences, Penninsula Allied Health Centre, Derriford Road, Plymouth, Devon, PL68BH

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Professor Jacqui Akhurst, Community Psychology, York St John University, Lord Mayor's Walk, York, YO31 7EX, UK

J.Akhurst@yorksj.ac.uk **Telephone:** 01904 876744

1.3 LANCASHIRE CARE FOUNDATION NHS TRUST SUPERVISOR:

Professor Max Marshall, Medical Director, Lancashire Care NHS Foundation Trust, Trust HQ, Sceptre Point, Sceptre Way, Walton Summit, Preston, PR5 6AW

Max.Marshall@lancashirecare.nhs.uk **Telephone:** 01772 773513

1.4 LEAD SPONSOR

Professor Graham Sewell, Head of School of Health Professions and Associate Dean, Faculty of Health and Human Sciences, Plymouth University, Faculty of Health and Human Sciences, Penninsula Allied Health Centre, Derriford Road, Plymouth, Devon, PL68BH

Gjsewell@Plymouth.ac.uk **Telephone:** 01752 588817

1.5 KEY COLLABORATORS

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A.bullock@nhs.net **Telephone:** 01642 838364

Sally Underwood, Occupational Therapy Professional Lead, Community Mental Health Services, Lancashire Care NHS Foundation Trust, North Barn, Pathfinder Dive, Lancaster, LA1 3JT
Sally.Underwood@Lancashirecare.nhs.uk **Telephone:** 01524 550568

1.6 RESEARCH AND DEVELOPMENT CONTACTS

Beverley Lowe, Research & Development Senior Officer, Lancashire Care NHS Foundation Trust, Research and Development Department, Medical Directorate, The Lantern Centre, Vicarage Lane, Fulwood, Preston , PR2 8DW

Beverley.lowe@lancashirecare.nhs.uk **Telephone:** 01772 773498

Jackie Mitchell, Research & Development Manager,.Tees Esk and Wear Valleys' NHS Trust, Research & Development Office, Flatts Lane Centre, Flatts Lane, NorManby, Middlesbourgh, TS6 OSZ

Jackiemitchell2@nhs.net **Telephone:** 01642283993

1.7 STEERING GROUPS

Researching Occupation Participation Effectiveness (ROPE)

The ROPE group is a collaboration of people throughout the country who are interested in fostering the development of effectiveness studies related to occupation and mental health; it has a wealth of experience in research, service user involvement work and occupational therapy. They are the steering group for the POINTER Study who peer review the Study and its progress, providing constructive critiques of its validity.

The Clinical Research Network (CRN): Mental Health FAST-R (Feasibility And Support to Timely recruitment for Research) Service. National Institute for Health Research.

1.8 RESEARCH ADMINISTRATOR

Michelle Greatorex, Lancashire Care NHS Foundation Trust.

North Barn, Pathfinder Drive, Lancaster LA1 3JT

Michelle.greatorex@lancashirecare.nhs.uk **Tel: 01524 550516**

2.0 STUDY OVERVIEW

2.1 Study background

The vision of NHS England is for everyone to have greater control of their health and wellbeing, supported to live longer, healthier lives by high quality health and care services that are compassionate, inclusive and constantly-improving (NHS England 2014). The International Classification of Functioning, Disability and Health (ICF) (2001), is a multipurpose classification system, providing a scientific basis for understanding and studying health and health-related states, outcomes and determinants (World health Organisation WHO 2001). It is complementary to the International Classification of Diseases; Tenth Revision (ICD-10), which classifies health conditions (e.g. diseases, disorders and injuries) (WHO 2001). It is recommended that the (Tenth Revision, ICD10) and the ICF (2001) are used alongside each other, to gain a greater understanding of the individual in the context of their overall health and well-being (WHO 2001). This relationship is complex and multi-faceted and involves an appreciation of how an individual's health condition interacts with who they are, and their particular life context, and consequently their quality of life. One of the core components of health is said to be the concept of 'participation', or "involvement in a life situation" as described in the ICF (2001), (WHO 2001, p.10). A particular issue with the concept of 'participation' in the ICF (2001) is that it is not well defined and conceptual clarity is lacking (Khetani and Coster 2007). The WHO (2001) identifies possible future directions for the development and application of the ICF (2001). To date, this has not been widely researched in relation to mental health. A systematic literature review on ICF publications identified that the most frequently researched clinical contexts were physical health conditions (Cerniauskaite et al 2011). There is no consensus about how participation is conceptualised so a systematic literature review was used to develop a definition for this study: Participation occurs when an individual is involved in activities, within the context of their life, which provides that person with a sense of engagement.

Personal recovery has been defined as a way of living a satisfying, hopeful and contributing life, even with the limitations caused by illness (Anthony 1993). Occupational therapy is concerned with the impact of illness on occupations/ functioning and levels of disability (dysfunction) caused, i.e. how a health condition interacts with who someone is and their particular life context, and consequently quality of life. The foundational beliefs of occupational therapy are based on the principles of occupation and participation, and the importance of these to the health and well-being of the individual and society (Baum 2003, Creek and Hughes 2008, Law 2002 and Reed et al 2013). A literature review on the effects of occupation on health identified that there was a wide range of research exploring the relationship between occupation and health, however there was limited knowledge about the

ways in which occupation influences health (Creek and Hughes 2008). Some studies put forward hypotheses about why health improvements occurred and more research was recommended to test these hypotheses.

This study is situated within mental health and particularly focussed on individuals who have a diagnosis of psychosis. There are significant consequences of being diagnosed with psychosis e.g. the effect of a diagnosis of schizophrenia, for individuals, their families and the wider society include; employment difficulties, high mortality rates, substantial family burdens and impoverished quality of life (Knapp et al 2004). The economic costs associated with treating people diagnosed with schizophrenia are also substantial. In an international literature review of the 'Costs of having a diagnosis of schizophrenia,' while the majority of the studies had been conducted in Europe and North America, it was estimated that the typical cost was between 1.5 per cent and 3 per cent of total national health care expenditure (Knapp et al 2004). Having more evidence about which treatment interventions are most effective at enabling people who have a diagnosis of psychosis to recover, could potentially reduce the personal and economic costs to individuals, their families, wider society, and the health service.

Importance of the topic

Occupational therapy, as defined by the World Federation of Occupational Therapy (WFOT), Council for Occupational Therapists in the European Countries (COTEC) and the British Association/College of Occupational Therapists (BAOT/COT), is an established therapy (COT 2013). Occupational therapists are recognised as one of the five key professions in the UK National Health Service who assist in the recovery of people with mental health problems (COT 2006). Occupational therapists are members of multi-disciplinary teams delivering mental health services to individuals with a diagnosis of psychosis, living in the community, including Early Intervention in Psychosis; Community Mental Health Teams and Assertive Outreach Teams (Department of Health 2001). The main aim of occupational therapy is to maintain, restore, or create a match, beneficial to the individual, between the abilities of the person, the demands of her/his occupations and the demands of the environment, in order to maintain or improve the client's functional status and access to opportunities for participation (Creek 2003, p.14). In their Position Statement the WFOT (2010) defines the primary goal of occupational therapy is to enable people to participate in everyday life through occupation (WFOT 2012). Despite the importance of participation as an outcome it is has not been widely used to assess the effectiveness of occupational therapy.

There are calls for more effectiveness studies in occupational therapy generally (Lin 2013 and Bannigan et al 2008) and, as applied to mental health specifically (COT 2006). Anecdotally occupational therapists delivering occupational therapy with people with a

diagnosis of psychosis, living in the community, are enabling them to improve their performance and satisfaction with their activities of daily life, in two separate NHS Trusts in the North of England; this is demonstrated through the analysis of standardised occupational therapy outcome measures. Occupational therapy has been defined as a complex intervention (Creek 2003). Accordingly its nature creates a greater challenge within effectiveness studies. There has been one pilot randomised controlled trial (RCT) of occupational therapy for people with psychotic conditions (Cook et al 2009). The major challenge of the study was contamination of the experimental intervention between the intervention and control groups, i.e. some participants in the treatment as usual group received occupational therapy (Cook et al 2009). Additionally the outcome measures used did not specifically measure participation; therefore inferences of effect on participation are difficult to ascertain. This is an area of practice that warrants further effectiveness research.

What will be gained from the Study?

There is dissatisfaction with the number and quality of trials of psychosocial interventions in mental health, relative to those of drug therapy, and there are claims that they have had insufficient impact on everyday clinical practice (Green 2006). One suggestion to support improvement is that the same rigour applied to efficacy trials in psychiatry, now needs to be applied to effectiveness trials (Tansella et al 2006). This Study utilises the Developing and evaluating complex interventions: new guidelines (Medical Research Council (MRC) 2008) to guide a robust research process. The long term aim is to develop a future pragmatic RCT to test the effectiveness of occupational therapy, at enabling individuals with a diagnosis of psychosis, living in the community, to improve their participation in activities of everyday life. There are a number of methodological uncertainties that need to be resolved, related to the description, utility and acceptability of the intervention and its measurement, before it is practicable to move to a feasibility study to assess issues such as sampling and recruitment. This Study will also contribute to the operationalization of the term 'participation', as a core component of the ICF (2001). It will use the best available evidence and appropriate theory and take a phased approach to test the key uncertainties in the design of a future pragmatic RCT (MRC 2008).

2.2 Aims and Objectives

This research aims to explore how feasible it is to carry out an effectiveness study, of occupational therapy, enabling individuals with a diagnosis of psychosis, living in the community, to improve their participation in activities of everyday life. Feasibility studies are studies conducted before a main study in order to answer the question "Can this study be done?" They are used to estimate important parameters that are needed to design the main study (National Institute for Health Research 2013). The Study is part of a carefully phased

approach to test key uncertainties in the design of an effectiveness study (MRC 2008) and has the following objectives:

1. To achieve a valid description of occupational therapy, with good utility for a pragmatic RCT.
2. To explore the level of fidelity to occupational therapy and to test out a method of measuring fidelity.
3. To explore participants' adherence to occupational therapy and test out a method of measuring adherence.
4. To measure participation in activities of everyday life and identify a valid method of measuring participation; with good utility for a pragmatic RCT.
5. To explore what indication of effect there is of occupational therapy, enabling individuals with a diagnosis of psychosis, living in the community to improve their participation in activities of everyday life.
6. To understand more about how occupational therapy enables people with a diagnosis of psychosis to participate in their activities of everyday life.

2.3 Design

Following the advice given by the 'Developing and evaluating complex interventions: new guidance' (MRC 2008) this Study is designed to explore how feasible it is to carry out an effectiveness study, of occupational therapy, enabling individuals with a diagnosis of psychosis, living in the community, to improve their participation in activities of everyday life? This Study will utilise a before-after design to test the key methodological uncertainties for a later pragmatic RCT. In a before-after study, the experimental group is exposed to the experimental variable (independent variable), and the dependent variable (e.g. health status) is measured before and after the intervention to measure the effects of the independent variable (Bowling 2009). As the ultimate aim is to carry out a pragmatic RCT this Study will model the occupational therapy pathway and outcome measurement, under the usual conditions in which it is applied, as per pragmatic RCT conditions (Thorpe et al 2009), without the control group. Outcome measure data will be collected at baseline and six months and process measures will be utilized throughout the Study (see section 6.0 Outcomes and Measurement).

2.4 Settings

The Study will recruit from adult mental health services in the North of England. The site based in the North East (Centre one) will be Tees, Esk and Wear Valleys NHS Foundation Trust and participants will be recruited from the Community Mental Health Teams and Early Intervention Services. The site based in the North West (Centre two) will be Lancashire Care NHS Foundation Trust and participants will be recruited from Community Mental Health

Teams and Assertive Outreach. All participants will be recruited from services which already provide occupational therapy as part of their service specification. The occupational therapy will take place in typical settings i.e. participants' own homes and communities, including mental health team bases.

2.5 Participants – inclusion and exclusion criteria

The Study aims to identify individuals who have a diagnosis of psychosis, with occupational/ functional needs and living in the community. The eligibility criteria, were designed to include typical participants as per pragmatic trials guidelines (Zwarenstein et al 2008).

Inclusion criteria

1. Individuals over the age of 18 years, with no upper age limit.
2. Individuals with a current primary diagnosis of psychosis (schizophrenia, schizo-affective disorder, psychotic depression or bipolar disorder), according to the clinical diagnosis in the clinical notes. Individuals with dual diagnosis or physical/sensory disabilities will be included.
3. Individuals will also have moderate to very severe occupational/ functional needs.

Exclusion criteria

1. Individuals with a diagnosis of an organic brain disorder or suspected organic cause to the psychosis.
2. Primary diagnosis of substance misuse.

2.6 Sample population and size:

Generally the aim of a sampling strategy is to achieve a representative sample of the target population from which it is drawn (Kendall 2003). This is a feasibility Study with two Centres, and the suggested target sample size for a pilot study is 30 participants in the intervention arm (Lancaster et al 2002). The Study will aim to recruit 64 participants, allowing for a dropout rate of approximately six percent; this aims to achieve a final sample of no lower than 60 participants (30 participants in each Centre). This sample size has been calculated by reflecting on the Cook et al (2009) study which was a pilot randomised controlled trial of occupational therapy for people with psychotic conditions and had a five per cent dropout rate and the study by Fowler et al (2009) which was a single-blind randomized controlled trial for improving social recovery in psychosis, which had an eight per cent drop out rate. The sample size also takes into consideration each occupational therapist (eight) in the Study having equal caseload sizes (eight participants) and minimising the burden on participants, to be involved.

3.0 POINTER STUDY ENROLMENT PROCESS

The POINTER Study enrolment process is shown in Figure 3.1 and describes the process of enrolling participants into the Study. The occupational therapists, research assistants and research administrator (who are separate to the main researcher) will manage this process. The researcher will oversee this process.

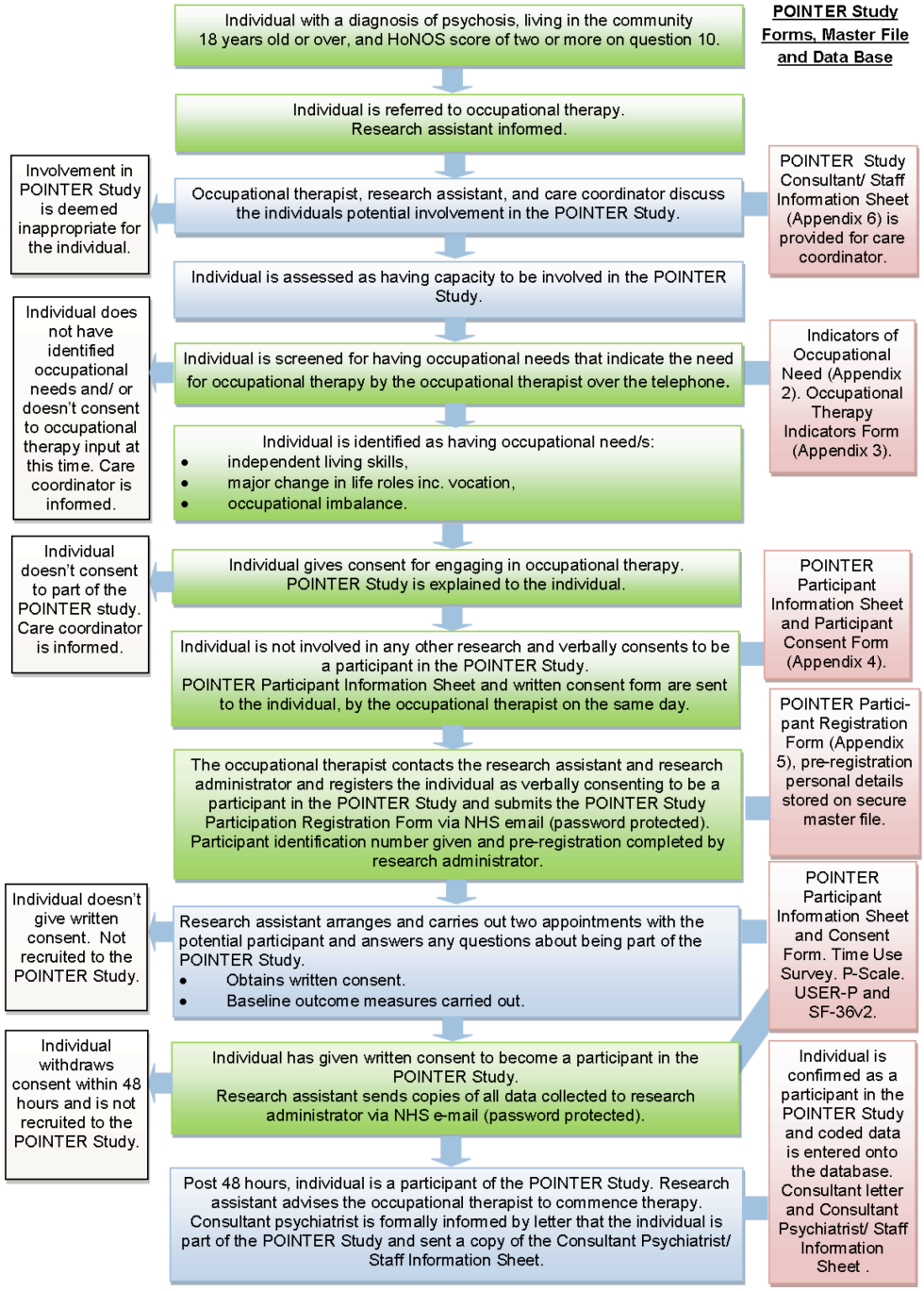
Notes

The HoNOS is an outcome measure of health and social functioning of people with severe mental illness and it is now the most widely used outcome measure in specialist mental health services in England and overseas (Royal College of Psychiatrists 2013). Participants will score two, three or four on question 10 of the HoNOS (two: a mild problem; three: definitely present and four: very severe problem) indicating a problem with activities of daily living; this is reflective of current practice to identify individuals who have occupational need which may benefit from occupational therapy.

Home visiting: Researchers and occupational therapists who need to carry out assessments in participants own homes or the community, will carry out these accordance with the Tees, Esk and Wear Valley NHS Foundation Trust's or Lancashire Care Foundation Trust policies relating to home visiting and personal safety. All researchers and occupational therapists will receive appropriate supervision and training for their roles. Additional support will be provided, should the researchers or occupational therapists experience any distress from talking to participants about their individual circumstances.

Figure 3.1 POINTER STUDY ENROLMENT PROCESS

3.1 POINTER Study Enrolment Process



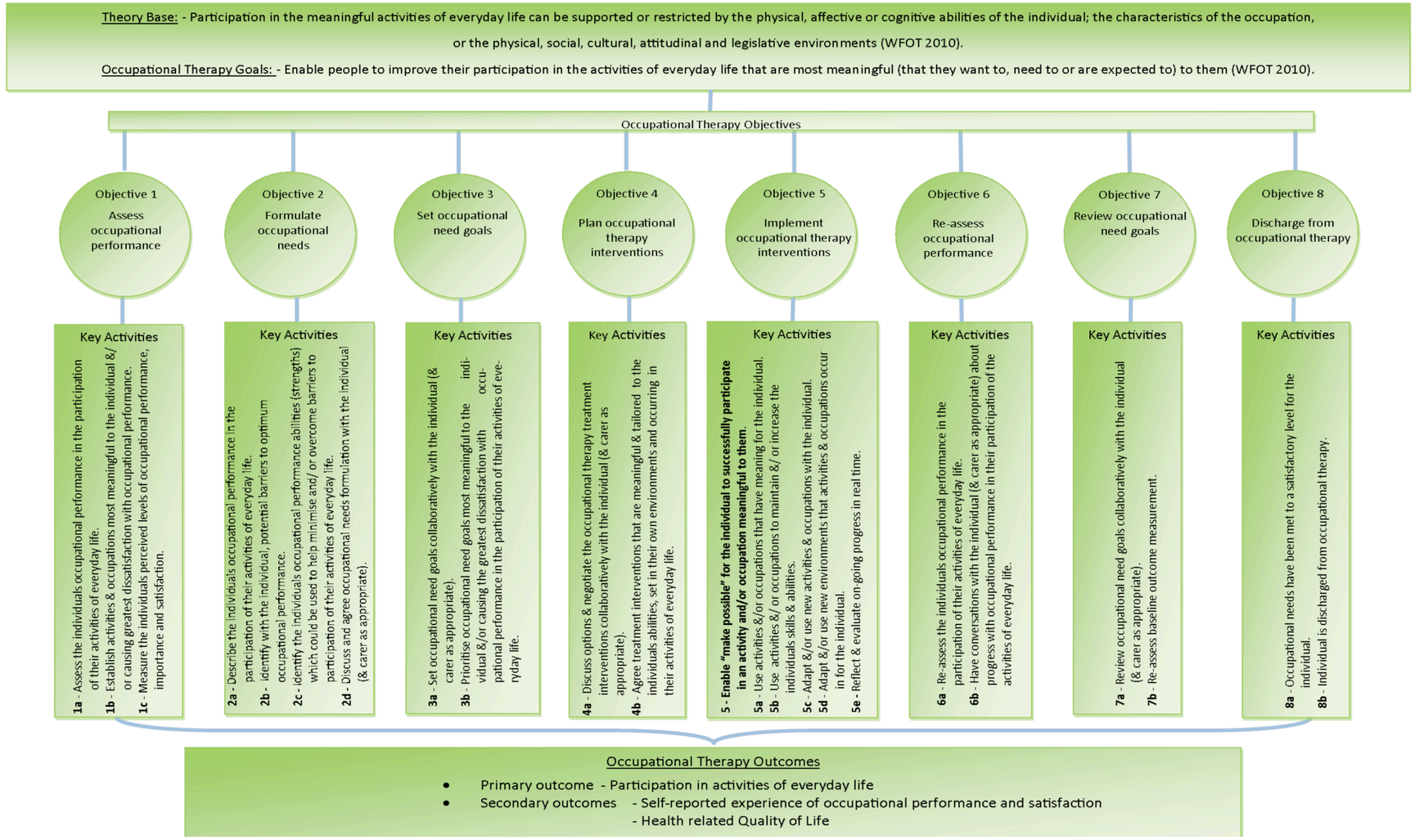
4.0 POINTER STUDY INTERVENTION: OCCUPATIONAL THERAPY

Occupational therapy is the POINTER Study intervention, a task analysis of the theory base, therapy goals, objectives and key activities and expected outcomes has been carried out as recommended by Giltlin (2013). This process utilized the MRC (2008) guidance to identify the evidence base and theory of occupational therapy, and to model the process and outcomes for application in a RCT. This involved critiquing the evidence base, including a detailed analysis of 'Occupational therapy defined as a complex intervention' (Creek 2003) and an occupational therapy intervention schedule for people with psychotic conditions (Cook and Birrell 2007). This was considered in the context of the 2010 Position Statement (WFOT 2012), the ICF (2001) description of health and health related states, which includes participation as one of the core components of health (WHO 2001) and current occupational therapy best practice with people with a diagnosis of psychosis in two NHS Trusts in the North of England. The task analysis was then critiqued by experts in the field, this included ROPE (see section 1.6); occupational therapy professional leads and clinicians in practice; students and staff who attended a York St John University academic research seminar; a professor in medicine; a clinical psychologist and service users from the CRN: Mental Health Fast-R Service, NIHR (see section 1.7) and following each critique appropriate amendments were made to the task analysis.

The Occupational therapy pathway can be seen in Figure 4.2, this outlines the objectives and key activities of occupational therapy that will **all** need to be provided for fidelity to the intervention. This will be delivered as a tailored approach to meet each individual participants occupational needs, the intervention will be provided face to face on a weekly or two-weekly basis (depending on need) and in the participants own home and/ or community (depending on need) and the occupational therapy will be provided by qualified occupational therapists (see section 5.0).

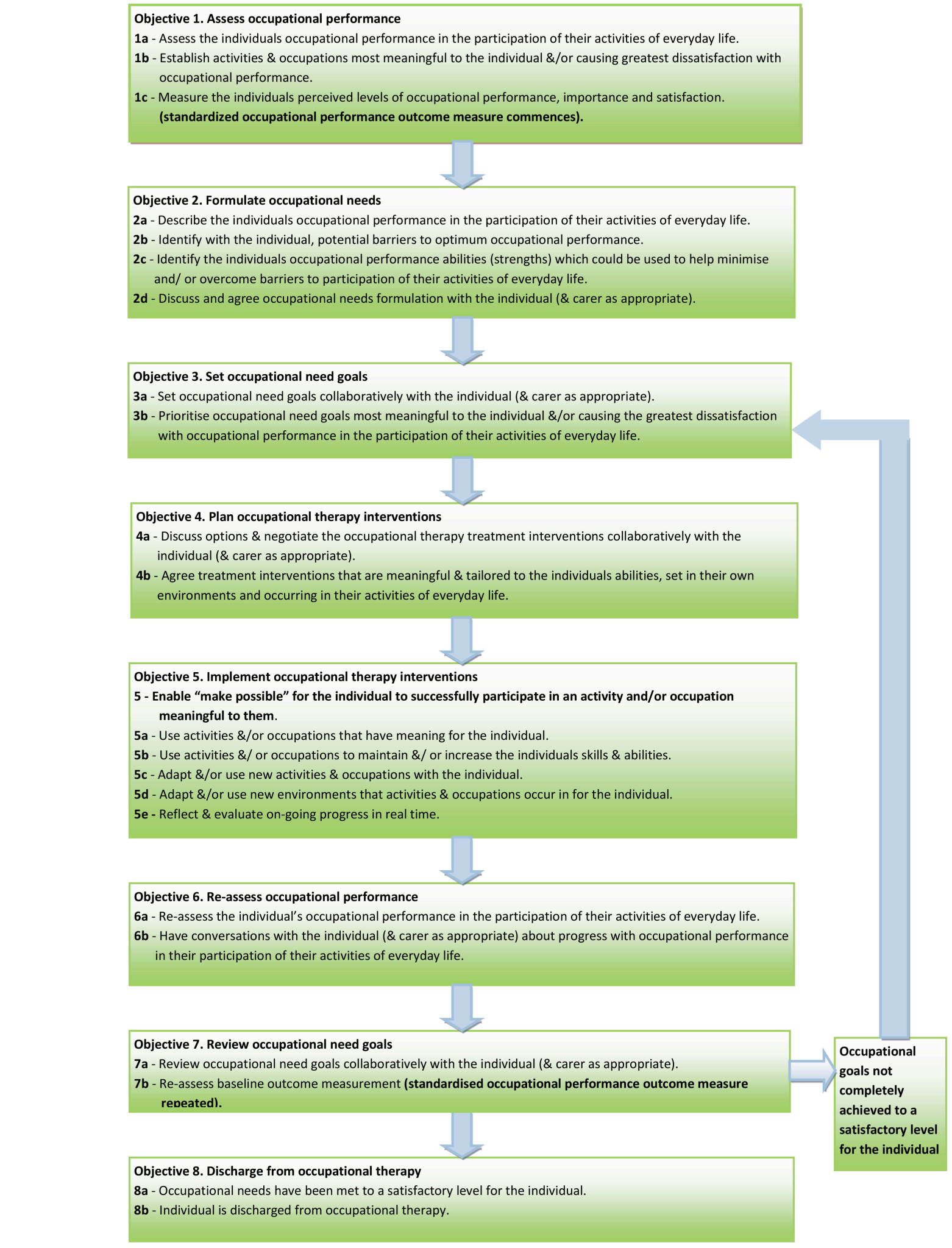
4.1 POINTER STUDY OCCUPATIONAL THERAPY TASK ANALYSIS

Figure 4.1 POINTER Study Occupational Therapy Task Analysis



4.2 POINTER STUDY OCCUPATIONAL THERAPY PATHWAY

Figure 4.2 POINTER Study Occupational Therapy Pathway



5.0 POINTER STUDY OCCUPATIONAL THERAPISTS

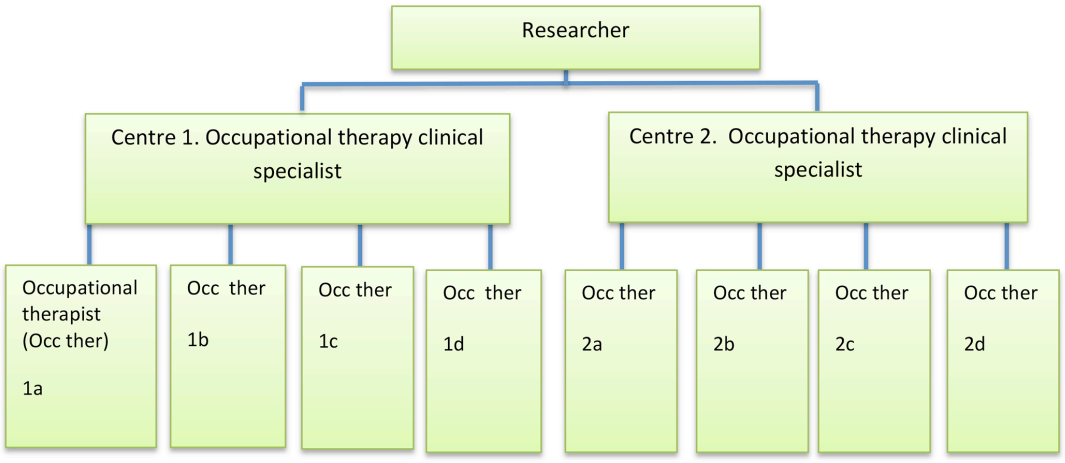
Occupational therapists will be qualified occupational therapists with Health Care Professions Council (HCPC) registration. Occupational therapists already providing occupational therapy in the two Centres (four from each) with people with a diagnosis of a psychosis, in the community, will carry out the occupational therapy, as per the POINTER Study occupational therapy protocol with eight participants each. The total number of occupational therapists will be eight. Occupational therapists will be selected and enrolled into the study in collaboration with the occupational therapy professional leads in the two Centres. A pragmatic approach will balance the area of expertise of the occupational therapists and the ability of the service to enable them to provide occupational therapy to individuals with a diagnosis of psychosis for the Study. The researcher will meet with each occupational therapist to go through the POINTER Study Occupational Therapist Information Sheet (see Appendix 8) and the POINTER Study Occupational Therapist Consent Form (see Appendix 9) and to gain written consent. Further consent will be gained for the focus group using the POINTER Study Occupational Therapists Focus Group Consent Form (see Appendix 10).

Training, support and supervision

The occupational therapists will be trained to follow the POINTER Study Protocol. This will support fidelity to the POINTER Study occupational therapy pathway and enable the data about what was provided to be recorded appropriately. The occupational therapists will start using the POINTER Study Protocol during a 'run-in' period to the study, before formal recruitment to the trial, to ensure that the intervention is provided effectively and recorded accurately (Campbell et al 2000).

Each Centre will have an occupational therapy clinical specialist (trained in use the POINTER Study Protocol) who will provide monthly professional supervision for the occupational therapists in relation to their POINTER Study occupational therapy caseload (see Figure 5.1). The researcher will provide monthly supervision for the occupational therapy clinical specialists. The researcher and the occupational therapy clinical specialists will keep a log of questions, queries and resolutions (see Appendix 12) in relation to the use of the POINTER Study Protocol. All occupational therapists will continue to receive their regular professional supervision.

Figure 5.1 POINTER Study occupational therapy supervision structure



6.0 OUTCOMES AND MEASUREMENT

The primary outcome is participation in activities of everyday life. There is no consensus about how participation is conceptualised so a systematic literature review was used to develop a definition for this study, i.e. 'Participation occurs when an individual is involved in activities, within the context of their life, which provides that person with a sense of engagement'. This definition was then used to review measures of participation and there was no reliable and valid measure of participation that could be used as the primary outcome measure for this study. The secondary outcomes are self-reported experience of occupational performance and satisfaction and health-related quality of life.

Part of the process of a feasibility study is to determine the most valid primary and secondary outcome measures; therefore multiple instruments for outcome measurement are being utilized and these have been kept to a minimum to manage the burden to participants. All outcomes and instruments for outcome measurement are listed below in Table 6.1.

Table 6.1. Outcome's and instruments for outcome measurement measures

Outcome's	Instruments for outcome measurement
Time spent in activities of everyday life	The Time Use Survey (adapted from the UK 2000 Time Use Survey; Short, 2006)
Participation	Participation Scale (P-Scale)
Participation	Utrecht Scale for Evaluation of Rehabilitation Participation (USER-P)
Self-reported experience of occupational performance, and satisfaction.	Canadian Occupational Performance Measure (COPM)
Health related Quality of Life	The Short Form – 36 Health Service Questionnaire (SF-36 v2)

Process measures will also be used to illuminate the explanation of results and to analyse the validity and reliability of the POINTER Study Protocol for a future pragmatic RCT.

6.1 Primary outcome measure

As there was no reliable and valid measure of participation that could be used as the primary outcome measure time use, i.e. an individual's involvement in activities, was used instead. Therefore the primary outcome measure for the indication of effectiveness is The Time Use Survey (adapted from the UK 2000 Time Use Survey; Short, 2006). This measure consists of a semi-structured interview in which participants are asked about how they have spent

their time over the past month (Fowler el al 2009, p.1631). Copies of the survey by Fowler et al (2009) were not available so a time use survey was adapted similarly from the UK 2000 Time Use Survey (Short, 2006).

6.2 Secondary outcome measures:
The secondary outcome measures (listed in Table 6.1) support the measurement of the primary outcome, its constructs and overall health related quality of life.

Assessment procedures:

Baseline outcome measurement

Baseline outcome measures will be completed with participants prior to commencing occupational therapy, by a research assistant. Research assistants will be trained to follow the enrolment process (see Figure 3.1) and use the instruments to measure the outcomes (see Table 6.1). The outcome measurement will be repeated when the participant is discharged from occupational therapy or at six months, and at this time the POINTER Study Participant Questionnaire will also be completed, by a research assistant. Participants will complete the COPM when they commence occupational therapy, repeating it as a minimum after six months with the occupational therapist.

Process measures
To enable the explanation of results, process data will be collected. The method used to do this will be similar to that used in a RCT protocol, which was developed for an effectiveness trial of occupational therapy in Parkinson's disease (Sturkenboom et al 2013). Participants' experiences with occupational therapy will be explored using the POINTER Study Participant Questionnaire when they are discharged or after six months of the occupational therapy, it includes questions on the experiences of the interaction with the therapist, the process and content of the intervention and the perceived effectiveness of the intervention.

After each face to face contact with the participant, the occupational therapists will record the intervention using the Recording Guidance (see Appendix 14). The location, duration, nature of the contact and the occupational therapy key activities delivered will be recorded and the occupational therapists will rate the participant's adherence to the therapy, on the POINTER Study Occupational Therapy Intervention Log (see Appendix 13). All POINTER Study occupational therapy intervention deviations will be recorded on the same log. This will provide insight into actual treatment delivery and indicate the overall level of fidelity to the POINTER Study occupational therapy. Fidelity to the POINTER Study Occupational Therapy Pathway (see Figure 4.2) will be assessed and monitored throughout the Study to ensure

that fidelity remains high throughout (West and Spring 2014). This will be carried out by the occupational therapy clinical specialists who will use the POINTER Study Occupational Therapy Fidelity Checklist (see Appendix 15), on a monthly basis with a random selection of two participants (25 per cent approximately) from of each occupational therapists caseload for that month. These assessments will be discussed during professional supervision to support fidelity and any concerns will be discussed with the researcher. At the end of the study's therapy intervention period, the occupational therapists will record their views about the effectiveness of the occupational therapy for the individual participant on the POINTER Study Occupational Therapy Intervention Log (see Appendix 13). At the end of the study, a focus group will be carried out in each of the Centres with all the occupational therapists who took part, to explore their experiences and views on using the POINTER Study Protocol, and thoughts about how to make it even more effective.

The occupational therapy clinical specialists and the researcher will maintain a POINTER Study Log of Questions/ Queries and Resolutions (see Appendix 12) from conversations with each other and the occupational therapists. Attempts will be made to resolve issues at the time and the learning will be used to improve the validity and reliability of a future pragmatic RCT. All information recorded will be coded showing only the occupational therapists identification number.

7.0 DATA COLLECTION

Process

Confidential participant information will be coded by the research administrator using a participant identification numbering system, to ensure that the identity of the participants' are kept anonymous. Data collected from participants will be the POINTER Study Participant Consent Form; socio-demographic data; scores from the primary and secondary outcome measures at baseline and six months and the POINTER Study Participant Questionnaire when they are discharged or after six months of occupational therapy.

Data collection will also include process data that codes the actual occupational therapy delivery. The occupational therapy clinical specialists will access participants' case notes to assess and monitor fidelity to the POINTER Study Occupational Therapy Pathway, using the POINTER Study Fidelity Checklist. Baseline outcome measures will be timed for how long they take to administer.

Each occupational therapist will be given an identification number. Data collected from and about the occupational therapists and their experiences will be socio-demographic data and the recording and transcripts of the focus group, this data will be made anonymous.

The POINTER Study Log of Questions/ Queries and Resolutions, related to the process of the study will be coded using the occupational therapists identification numbers. The researcher will monitor the data inputting for completeness on a weekly basis and will contact the occupational therapy specialists and research assistants regarding any missing data.

Data storage and contact details

All written confidential data collected will be sent via NHS emails with password protection to the POINTER research administrator: Michelle.Greatorex@Lancashirecare.nhs.uk and stored on a master file with password protection. All written data will be stored securely on the NHS computer system. The audio tapes from the focus groups will be stored securely on an NHS premises and transcribed by the research administer. The transcriptions will also be stored securely on the NHS computer system. Once the study is completed the primary data will be stored securely at the University for 10 years.

8.0 DATA ANALYSIS:

The data analysis of feasibility studies is not designed to detect treatment effect (Lancaster et al 2002). The analysis will be focused on exploring and testing key uncertainties for a potential future pragmatic RCT (which will be conducted based on the findings of this study) of the effectiveness of occupational therapy at improving the participation of people with a diagnosis of psychosis, living in the community. The data analysis will use a combination of quantitative and qualitative approaches. Some statistical tests will be applied to test the construct validity of the method of measuring participation and to give an indication of effect of occupational therapy on the participation of everyday activities. The quantitative data will be analysed using descriptive and inferential statistics. As the study has not been powered a descriptive analysis of changes with a calculation of the effect size will be conducted. A comparison of the pre- and post-intervention scores will be made, i.e. the normality of measures will be tested using a kologomorov-smirnov test/ shaper-wilks test. If the data is normally distributed then the primary outcome measure of time use will be assessed using a paired t-test. As the secondary measures are ordinal scales so a non-parametric wilcoxin signed ranks test will be used. A spearman's test will be used for the planned correlation between participation measures and the COPM. The content analysis of the qualitative data will take an inductive approach as there is not enough former knowledge about the application of occupational therapy as applied to mental health trials (Elo and Kyngas 2008). The analysis will be considered collectively to explore and determine the feasibility of a future pragmatic randomised controlled trial (post POINTER study).

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Participation through Occupational INTervention Effectiveness Research (POINTER) Study Participant Information Sheet

Study Title: The effectiveness of occupational therapy at enabling people with a diagnosis of psychosis, living in the community, to improve participation in their activities of everyday life.

Researcher: Joanne Inman, PhD Student

Supervisors: Dr Katrina Bannigan and Professor Jacqui Akhurst

We would like to invite you to take part in our research Study. Before you decide we would like you to understand why the research is being done and what it would involve for you. **One of our team will go through the information sheet with you and answer any questions you have**. We'd suggest this should take about twenty minutes. Talk to others about the Study, e.g. your carer/s, friends or family if you wish and take time to decide whether you would like to take part.

What is the purpose of the Study? This Study is being carried out as a clinical research study for a PhD. It is exploring how occupational therapy enables individuals with a diagnosis of psychosis, living in the community, to improve participation in their activities of everyday life? Occupational therapy uses purposeful activity to prevent disability and promote health and independent function. Participation is defined as occurring when you are involved in activities, within your life, providing you with a sense of engagement. The Study also tests out how possible it would be, to carry out a larger study in the future.

Why have I been invited? You have been invited to take part in this Study, because you have been identified as having some difficulties with your everyday activities and occupational therapy may be able to help you overcome these.

Do I have to take part? It is up to you to decide if you want to join the Study. If you do, you are free to withdraw at any time, without giving a reason. This will not affect your standard of care.

What will happen to me if I take part? A research assistant will meet with you wherever is most convenient for you before you start receiving occupational therapy and after you have

been discharged or after six months, this will be two visits on both occasions, each lasting approximately an hour each. On the visits before the Study they will go through the information sheet with you, if you wish to be involved in the study you can complete the written consent form and you will still have up to 48 hours to change your mind. The research assistant will also ask you some questions about your participation in activities of everyday life, your quality of life and also about your experiences of occupational therapy, this information will be recorded on different assessment forms, your identity will be anonymised on these and this information will be submitted to the research administrator.

When you start receiving occupational therapy will work with a dedicated occupational therapist. The focus will be on the activities of daily life that are most meaningful to you, causing you dissatisfaction and that you would like to participate in even more. E.g. you may be supported to be able to cook for yourself, return to participating in a favourite hobby or to be able to leave the house to do your own shopping. You will discuss and agree your goals collaboratively with your occupational therapist, including how much support you need to achieve these; you will see your occupational therapist either weekly or fortnightly depending on what you agree you need to reach your goals. The occupational therapist will record these interventions in your case notes and will submit an anonymised overview of your intervention to the research administrator.

The occupational therapy will be provided alongside all other interventions agreed in your care plan. The occupational therapist will become part of your care team.

What are the possible disadvantages of taking part? You will have some extra questions to answer with a research assistant, who will visit you before the Study starts and after you have finished occupational therapy or after six months.

What are the possible benefits of taking part? You will get the opportunity to work towards your personal goals around your activities of daily life. The information we get from this Study will help improve the interventions used to enable people with a diagnosis of psychosis to recover.

What happens when the Study stops? Data about your occupational therapy will no longer be collected for the Study. If you are satisfied that you have met your goals, you will be discharged from occupational therapy. If you still require occupational therapy, it will continue to be provided for you as part of your care plan. All other care on your care plan will continue.

Will my taking part in the Study be kept confidential? Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. All information collected about you during the Study will be anonymised. All information will be stored securely.

Your consultant psychiatrist will be informed of your involvement in the Study.

If you provide any information which indicates that you may be a risk to yourself or others, or that harm has been caused to another person or persons, your confidentiality will be broken.

If you join the Study, some of your medical records and the data collected for the Study will be looked at by authorised members of the research team. They may also be looked at by authorised people to check, that the Study is being carried out correctly. We shall respect your confidentially as a research participant and we will do our best to meet this duty.

What if new information becomes available? Sometimes we get new information about treatment being studied. If this happens one of our team will tell you and discuss whether you should continue in the Study. If you decide to continue in the Study you may be asked to sign an agreement outlining the discussion.

What will happen if I don't want to carry on with the Study? If you withdraw from the Study, we will need to use the data collected up to your withdrawal. This would not affect the standard of care you receive.

What if there is a problem? If you have a concern about any aspect of this Study, you can ask to speak to the researcher who will do her best to answer your questions (Joanne Inman 01524 550568 or Joanne.Inman@Lancashirecare.nhs.uk). If you remain unhappy and wish to complain formally, you can do this through the Research Supervisor, email: Katrina.Bannigan@Plymouth.ac.uk

If you need any independent help or advice on making a complaint, the Advocacy Services can help you and can be contacted as follows:

Patient Advice and Liaison Service (PALS) (for service users of Tees, Esk and Wear Valleys NHS Foundation Trust): staff are available Monday to Friday, 9am-4pm.
Tel: 0800 052 0219 (free phone)
Mobile: 07775 518 086
Email: **tewv.pals@nhs.net**
Post: PALS team, Flatts Lane Centre, Normanby Middlesbrough, TS6 0SZ

Advocacy Access (for service users of Lancashire Care NHS Foundation Trust)
Tel: 0345 456 3210

Text Phone: 07886 744 634
Fax: 0300 323 0966
Email: contact@advocacyaccess.org.uk

Empowerment (for Blackpool residents of Lancashire Care Foundation NHS Trust), 6a Skyways, Amy Johnson Way, Myraid House, Blackpool, FY4 2RP
Tel: 01253 405959
Email: admin@empowermentcharity.org.uk
Web: www.empowermentcharity.org.uk

What will happen to the results of the Study? Anonymised results of the Study may be published in scientific journals, presented at conferences or written in reports to NHS managers and clinical leads. All participants in the Study will receive a copy of the findings. The results of the Study will be presented to staff and service users in your NHS Trust.

Who is organising and funding the Study? The Study is being organised through Plymouth University and funded by a PhD studentship.

Who has reviewed the study? All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by …….. Research Ethics Committee on: ……..

The CRN: Mental Health FAST-R (Feasibility And Support to Timely recruitment for Research) Service. National Institute for Health Research.

Further information and contact details

If you require further information, please contact: Joanne Inman, North Barn, Pathfinder Drive, Lancaster, LA1 4JJ, Tel: 01524 550568

Participant to be given a copy of this Form

Lancashire Care NHS
NHS Foundation Trust

Appendix 2

Indicators of occupational need:- *a brief guide to what may indicate service user need for occupational therapy helping people lead ordinary lives in extraordinary circumstances (shared with permission from LCFT)*

Indicators of Occupational Need

Occupational therapy focuses on the nature, balance, pattern and context of occupations and activities in the day-to-day lives of individuals, family groups and communities. It is concerned with the meaning and purpose people place on occupations and activities, and with the impact of illness, disability and social or economic deprivation on their ability to carry them out. Occupational therapy uses the knowledge that the relationship between occupation and health is reciprocal – individuals experiencing health problems will likely see it impact on their abilities and occupational performance, whereas positive occupational experience and success undertaking activities carries health benefits and promotes recovery, thus helping people successfully resume ordinary lifestyles despite extraordinary circumstance.

The main aim of occupational therapy is to maintain, restore, or create a match, beneficial to the individual, between the:

- *abilities of the person,*
- *the demands of her/his occupations*
- *the demands of the environment*

The desired outcome of occupational therapy intervention is that the person achieves a *satisfying performance, and balance of occupations, in the areas of self care, productivity and leisure*, that will support recovery, health, wellbeing and social participation (Creek 2003).

To achieve this, the therapist looks with the service user at her/his *range and balance of occupations,* and together they identify problems, deficits, and strengths. The therapist then narrows her/his focus of attention and works on the specific *activities*, *tasks* or *skills* that will best utilise the individual's assets, remediate deficits, and enable the person to enact her/his occupations more effectively. Where this is not possible, the therapist will adapt the desired activity so the individual is able to carry it out, or help make changes to their client's physical, cultural, institutional or social environments to facilitate occupational performance. The therapist then shifts the focus outwards again, to see what effect the action has had on the person's overall pattern of occupations. This shift of perspective happens many times during the period of contact between occupational therapist and service user (Creek 2003).

Where teams have access to occupational therapy, it is likely to be a limited resource. This can mean the occupational therapist becomes overwhelmed with demand for in-put or conversely, due to unfamiliarity with what can be provided, or belief that the resource cannot be accessed, colleagues may rarely make specific demands for occupational investigation (be it through consultation; full assessment; short or longer term intervention, or any combination of these things) . Discussion with occupational therapists, managers and team leaders is developing consensus on what constitutes a priority for occupational therapy input, The following summary is to assist teams identify when a person might benefit from occupational assessment or intervention.

There are three overriding conditions identified as necessary components for occupational therapy to progress appropriately:

- that the individual can articulate *some level of dissatisfaction* regarding the balance, range and meaningfulness of their day-to-day activities, and/or their level of ability in performing occupations; or in circumstances where the service user does not have insight or capacity to express such dissatisfaction, the carer/family member may themselves do so;

Refs: Creek J (2003) *Defining occupational therapy as a complex intervention* College of Occupational Therapists, London
Wilcock A (2006) *An occupational perspective of health (2nd edition)* Slack New Jersey, USA

- that the person with capacity to consent, does *consent to the occupational therapy* intervention; where the person does not have capacity, the therapist is required to observe for signs of implied consent and act accordingly;

- that there is a *likelihood of the person benefiting* from the intervention.

The following represents key indicators suggesting a **consultation** with an occupational therapist be sought, an **assessment** offered if appropriate, and where indicated, **interventions** provided. This flow represents the order of priority given to the indicators of need:

Occupational assessment should be considered where there is:

Urgent need for person to maintain dignified independence in daily living skills, or increase level of safe functioning

For example: Where mental illness or cognitive impairment severely impacts on independent living skills; level of support has changed/will imminently change; carers unable to continue with level of input; environmental change necessitates increased independence

And/or

Marked limitation to range of occupations- severe imbalance between occupational domains

For example: All/most of the person's energy taken up in one area of life resulting in very impoverished lifestyle & range of experiences in other areas; marked dissatisfaction with current occupations expressed as frustration, boredom, and very low esteem & sense of self-efficacy that may arise from loss of independence and reduced choices;

And/or

Major change in life role/threat to role

For example: loss of sense of purpose and few opportunities to be productive; impact of serious or multiple illnesses requiring marked role adaptation/re-assessment of future plans; changes in family structure; repeated losses of friends and opportunities; loss, or threat of loss, or

In addition to direct input with individuals working to meet identified occupational goals, the occupational therapist will prioritise working as part of the team contributing expertise on the following issues:

- Promoting healthy lifestyles;
- Protecting and promoting peoples' opportunities for social inclusion;
- Developing teams' insights into identifying and addressing occupational risk (Wilcock 2002), working so that the relationship between health and occupation is more fully understood and made use of.

We hope the above is helpful in highlighting when to explore occupational performance in more detail, and welcome discussion of service users' potential needs following consideration of the above factors.

Refs: Creek J (2003) *Defining occupational therapy as a complex intervention* College of Occupational Therapists, London

Wilcock A (2006) *An occupational perspective of health (2nd edition)* Slack New Jersey, USA

Lancashire Care NHS
NHS Foundation Trust

Occupational Therapy Indicators Form

This form is shared and adapted with permission from LCFT

Name: NHS Number:	Team: Date:

This form should be used to help identify whether occupational therapy is indicated

Information from: CPA documents ☐ Service user ☐ Carer ☐ MDT ☐

Are any of the following factors present?

Priority level 1 - Occupational Therapy role	Yes	Maybe	No
Is there urgent demand for the person to increase their level of independent living skills? For example: Where mental illness or cognitive impairment severely impacts on independent living skills; level of support has changed/will imminently change; carers unable to continue with level of input; environmental change necessitates increased independence. **Notes:**			
Is there major change in life role/ threat to role? For example: loss of sense of purpose and few opportunities to be productive; impact of serious or multiple illnesses requiring marked role adaptation/re-assessment of future plans; changes in family structure; repeated losses of friends and opportunities; loss, or threat of loss, or change to, or take-up of work roles. **Notes:**			
Is there severe limitation to range of occupations or occupational imbalance? For example: All/most of the person's energy taken up in one area of life resulting in very impoverished lifestyle & range of experiences in other areas; marked dissatisfaction with current occupations expressed as frustration, boredom, and very low esteem & sense of self-efficacy that may arise from loss of independence and reduced choices; **Notes:**			

Priority level 2 – For all mental health workers	Yes	Maybe	No
Promote healthy lifestyles			
Protect and promote opportunities for social inclusion			

IS THERE AN IDENTIFIED NEED FOR OCCUPATIONAL THERAPY?

Yes:
Occupational needs may be indicated. Further occupational therapy assessment required and service user consents to same ☐

Yes:
Occupational needs may be indicated and further occupational therapy assessment advised BUT the service user does not wish to proceed and therefore no further appointments made at this time. ☐

No:
No occupational needs identified at this time. Consider opportunity for all mental health workers to promote priority level 2 activities. ☐

Occupational therapists notes:

Recommendations/Action required:

Occupational Therapist Name:

Date:

Appendix 4

Joanne Inman
North barn
Pathfinder Drive
Lancaster, LA1 3JT
Tel: 01524 550568

HEALTH PROFESSIONS WITH PLYMOUTH UNIVERSITY

Lancashire Care NHS Foundation Trust

Centre Number: Participant Identification Number:

POINTER Study Participant Consent Form August 2014

Study Title: Effectiveness of occupational therapy at enabling people with a diagnosis of psychosis, living in the community, to improve the participation in their activities of everyday life; a feasibility study

Researcher/Chief Investigator: Joanne Inman

Participant's Statement:

1. I confirm that I have read and understand the POINTER Study Participant Information Sheet, August 2014 for the above Study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactory. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I agree to receive occupational therapy. ☐
4. I accept that my consultant psychiatrist will be informed of my involvement in the Study. ☐
5. I understand that relevant sections of my medical notes and data collected during the Study may be looked at by individuals from the research team or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
6. I understand that if I provide any information which indicates that I may be at risk to myself or others, or that harm has been caused to another person or persons, my confidentiality will be broken. ☐
7. I give my permission to use quotes from me and I understand that these will be anonymised. ☐
8. I agree to take part in the above Study. ☐

| --- | --- | --- |
Name of participant	Date	Signature
Name of person taking consent	Date	Signature

When completed; 1 for participant; 1 for researcher site file; 1 for medical notes

HEALTH PROFESSIONS WITH PLYMOUTH UNIVERSITY

Lancashire Care NHS
NHS Foundation Trust

POINTER Study Participant Registration Form
CONFIDENTIAL

Participant identification number (to be added by the research administrator):

Name	
NHS Number:	
Age	
Diagnosis (as recorded in the clinical notes)	
Length of time since diagnosis in years and months	
Secondary diagnosis	Yes/ No
Care cluster	
HoNOS score question 10	
Identified as having occupational needs	Yes/No Date:
Employment status	
Previous experience of occupational therapy:	Yes/ No
Verbal consent to be in the POINTER Study	Yes/No Date:
POINTER Participant Information sheet and consent form sent to individual	Yes/No Date:

Occupational therapist identification number:

Date:

Joanne Inman
North Barn
Pathfinder Drive
Lancaster, LA1 4JJ
Tel: 01524 550568

Participation through Occupational INTervention Effectiveness Research

(POINTER) Study Consultant Psychiatrist/ Staff Information Sheet

Study Title: The effectiveness of occupational therapy at enabling people with a diagnosis of psychosis, living in the community, to improve participation in their activities of everyday life.

Researcher: Joanne Inman, PhD Student

Supervisors: Dr Katrina Bannigan and Professor Jacqui Akhurst

What is the purpose of the Study? This Study is being carried out as a clinical research study for a PhD. It is exploring how occupational therapy enables individuals with a diagnosis of psychosis, living in the community, to improve participation in their activities of everyday life? Occupational therapy uses purposeful activity to prevent disability and promote health and independent function. Participation is defined as occurring, when an individual is involved in activities, within the context of their life, which provides that person with a sense of engagement. The Study also tests how possible it would be, to carry out a larger study in the future.

Why was the service user selected to be involved in the Study? The service user was selected to be involved in the Study because they were identified as having some difficulties with their everyday activities and occupational therapy may be able to help them overcome these.

What will happen to the service user who is taking part in the Study? A research assistant will meet with the service user wherever is most convenient for them, before they start receiving occupational therapy and after they have been discharged or after six months. This will be two visits on both occasions, lasting approximately an hour each. Before being recruited into the Study they will go through the information sheet with the service user and if they wish to be involved in the Study they will complete the written consent form, they will have up to 48 hours to change their mind. The research assistant will also ask them some questions about their participation in activities of everyday life, their quality of life and also about their experiences of occupational therapy, this information will be recorded on different

assessment forms, their identity will be anonymised on these and this information will be submitted to the research administrator.

The service users will work with a dedicated occupational therapist from your team, to receive occupational therapy. The focus will be on the activities of everyday life that are most meaningful to them, causing them dissatisfaction and that they would like to participate in even more. E.g. they may be supported to be able to cook for themselves, return to participating in a favourite hobby or to be able to leave the house to do their own shopping. The service user will discuss and agree their goals collaboratively with the occupational therapist, including how much support they need to achieve these; they will see their occupational therapist either weekly or fortnightly depending on what the service user and occupational therapist agree is needed for them to reach their goals. The occupational therapist will record these interventions in the case notes and will submit an anonymised overview of their intervention to the research administrator.

The occupational therapy will be provided alongside all other interventions agreed in the service users care plan.

What are the possible disadvantages to the service user from taking part? The service user will have some extra questions to answer with a research assistant, who will visit them before the Study starts and after they have finished occupational therapy or after six months.

What are the possible benefits of taking part? The service user will get the opportunity to work towards their personal goals around their activities of daily life. The information we get from this Study will help improve the interventions used to enable people with a diagnosis of psychosis to recover.

What happens when the Study stops? Data about their occupational therapy will no longer be collected for the Study. If the service user is satisfied that they have met their goals, they will be discharged from occupational therapy. If they still require occupational therapy, it will continue to be provided as part of their care plan.

How will the Study maintain the service user's confidentiality? We will follow ethical and legal practice and all information about the service user will be handled in confidence. All information collected about them during the Study will be anonymised. All information will be stored securely. Some of the service user's medical records and the data collected for the Study will be looked at by authorised members of the research team to check that the Study is being carried out correctly. All will have a duty of confidentiality and we will do our best to meet this duty.

If a service user provides any information which indicates that they may be a risk to themselves or others, or that harm has been caused to another person or persons, this will be escalated to the care team.

What if new information becomes available? Sometimes we get new information about treatment being studied. If this happens one of our team will tell the service user and discuss whether they should continue in the Study. If they decide to continue in the Study they may be asked to sign an agreement outlining the discussion.

What will happen if the service user doesn't want to carry on with the Study? If the service user withdraws from the Study, we will need to use the data collected up to their withdrawal.

What if there is a problem? If you have a concern about any aspect of this Study, you can ask to speak to the researcher who will do her best to answer your questions (Joanne Inman 01524 550568 or Joanne.Inman@Lancashirecare.nhs.uk). If you remain unhappy and wish to complain formally, you can do this through the Research Supervisor, email: Katrina.Bannigan@Plymouth.ac.uk

What will happen to the results of the Study? The anonymised results of the Study may be published in scientific journals, presented at conferences or written in reports to NHS managers and clinical leads. All participants in the Study will receive a copy of the findings. The results of the Study will be presented to staff and service users in your NHS Trust.

Who is organising and funding the Study? The Study is being organised through Plymouth University and funded by a PhD studentship.

Who has reviewed the study? All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by …….. Research Ethics Committee on: ……..

The CRN: Mental Health FAST-R (Feasibility And Support to Timely recruitment for Research) Service. National Institute for Health Research.

Further information and contact details

If you require further information, please contact:

Joanne Inman, North Barn, Pathfinder Drive, Lancaster, LA1 4JJ
Tel: 01524 550568

HEALTH PROFESSIONS WITH PLYMOUTH UNIVERSITY

Lancashire Care NHS Foundation Trust

Insert address and telephone number of the research assistant.

Insert consultant psychiatrist name and address in here.

Date

RE: Service users name and address in here

Dear insert consultant psychiatrist's name,

The above service user has consented to take part in the Participation…through Occupational Intervention effectiveness Research (POINTER) Study and will be receiving occupational therapy from insert name of the occupational therapist, occupational therapist in your Team. For your information please find the POINTER Study Consultant Psychiatrist/ Staff Information Sheet enclosed.

If you have any further questions or queries, please contact insert name of occupational therapist, occupational therapist.

Yours sincerely,

Name of research assistant inserted here

Research assistant

Copy to be put in the service users medical notes

Joanne Inman
North Barn
Pathfinder Drive
Lancaster, LA1 4JJ
Tel: 01524 550568

Participation through Occupational INTervention Effectiveness Research (POINTER) Occupational Therapist Information Sheet

Study Title: The effectiveness of occupational therapy at enabling people with a diagnosis of psychosis, living in the community, to improve participation in their activities of everyday life.

Researcher: Joanne Inman, PhD Student

Supervisors: Dr Katrina Bannigan and Professor Jacqui Akhurst

We would like to invite you to take part in our research Study. Before you decide we would like you to understand why the research is being done and what it would involve for you. **The researcher will go through the information sheet with you and answer any questions you have.** We'd suggest this should take about twenty minutes. Talk to others about the Study if you wish and take time to decide whether you would like to take part. Ask us if there is anything that is not clear.

What is the purpose of the study? This Study is being carried out as a clinical research study for a PhD. It is exploring how occupational therapy enables individuals with a diagnosis of psychosis living in the community to improve participation in their activities of everyday life? Participation is defined as occurring, when an individual is involved in activities, within the context of their life, which provides that person with a sense of engagement. The Study also tests how possible it would be to carry out a pragmatic randomised controlled trial in the future.

Why have I been invited? You have been invited to take part in this Study because you have been identified as already providing occupational therapy to individuals with a diagnosis of psychosis, living in the community, as a routine part of your current practice.

Do I have to take part? It is up to you to decide if you want to join the Study. If you do, you are free to withdraw at any-time, without giving a reason. A decision to take part or not, will not affect your employment.

What will happen to me if I take part?

1. You will be provided with one and a half day's training in the use of the POINTER Study Protocol, which will go through the processes in detail for you and answer any questions that you have.
2. Basic demographic information will be collected from you.
3. You will receive monthly professional supervision from an occupational therapy clinical specialist in relation to your POINTER Study occupational therapy caseload.
4. You will be expected to screen for and provide occupational therapy to eight POINTER participants for up to six months each, as part of your regular caseload size expectations.
5. You will be expected to provide summary data at the end of each occupational therapy intervention, taking approximately 10 minutes. At the end of occupational therapy or at six months with each POINTER participant, you will rate the effectiveness and identify what hindered and facilitated the intervention.
6. Once the Study is 'live' your main questions/ queries and resolutions about providing occupational therapy as part of the Study will be recorded through discussions with your occupational therapy clinical specialist, this data will be anonymised.
7. You will be asked to take part in a focus group with the other occupational therapists taking part of the Study in your Centre, this will take place after each of your POINTER participants have met their goals or completed six months of occupational therapy; the purpose will be to talk about your experiences and learning from the Study. This will be recorded and transcribed and the data will be anonymised.

What will I have to do? Fully engage in the POINTER Study Protocol training. Follow the Protocol with eight POINTER participants and engage in monthly professional supervision regarding this work. Provide basic demographic information about yourself. Take part in a focus group about the Study.

What are the possible disadvantages of taking part? Being part of the Study will take a little bit more of your time to screen occupational therapy referrals for the Study. You will have an extra form to complete after each occupational therapy intervention, taking approximately 10 minutes. There will also be a focus group discussion.

What are the possible benefits of taking part? The information we get from this Study will help increase the knowledge base about occupational therapy and its relationship to improving participation in activities of everyday life, for individuals with a diagnosis of psychosis living in the community. The Study is foundational work for a future pragmatic randomised controlled trial.

This is an opportunity to be part of an applied clinical research study as part of your continuing professional development

What happens when the Study stops? If any of your POINTER participants have a continued need for occupational therapy they will continue on your caseload, however no further information will be collected for the Study.

Will my taking part in the Study be kept confidential? Yes. We will follow ethical and legal practice and all information about you and from you will be handled in confidence. All information collected about you and from you during the Study will be anonymised. All information will be stored securely.

If you join the Study, some of the medical records you have written and the data collected for the Study will be looked at by authorised members of the research team. They may also be looked at by authorised people to check, that the Study is being carried out correctly. All will have a duty of confidentiality to you as an occupational therapist and the POINTER participants and we will do our best to meet this duty.

What if new information becomes available? Sometimes we get new information about treatment being studied. If this happens one of our team will tell you and discuss whether you should continue in the Study. If you decide to continue in the Study you may be asked to sign an agreement outlining the discussion.

What will happen if I don't want to carry on with the Study? If you withdraw from the Study, we will need to use the data collected up to your withdrawal. We will organise for an occupational therapist to replace you in the Study.

What if there is a problem? If you have a problem or concern about any aspect of the Study, you can discuss this with the occupational therapy clinical specialist who is supervising you. Additionally the researcher (Joanne Inman tel: 01524 550568 or email: Joanne.Inman@lancashirecare.nhs.uk) will do her best to answer any unresolved questions. If you remain unhappy and wish to complain formally, you can do this through the Research Supervisor, email: Katrina.Bannigan@Plymouth.ac.uk

Involvement of POINTER participants Consultant The consultant will be informed of the POINTER participant involvement in the Study.

What will happen to the results of the Study? The results of the Study will be anonymised and some of the analysis will compare the two centres; however you will not be compared individually against other occupational therapists. The anonymised results of the Study may

be published in scientific journals, presented at conferences or written in reports to NHS managers. The results of the Study will be presented to staff and Service Users in your NHS Trust. All occupational therapist and POINTER participants will receive a copy of the findings.

Who is organising and funding the Study? The Study is being organised through Plymouth University and by a PhD studentship.

Who has reviewed the Study? All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by …….. Research Ethics Committee on: ……..

The CRN: Mental Health FAST-R (Feasibility And Support to Timely recruitment for Research) Service. National Institute for Health Research.

Further information and contact details

If you require further information, please contact: Joanne Inman, North Barn, Pathfinder Drive, Lancaster, LA1 4JJ

Tel: 01524 550568

Occupational therapist to be given a copy of this Form

POINTER Study Occupational Therapist Consent Form.

Joanne Inman
North Barn,
Pathfinder Drive
Lancaster, LA1 3JT
Tel: 01524 550568

Centre Number: Occupational Therapist Identification Number:

POINTER Study Occupational Therapist Consent Form

Study title: Effectiveness of occupational therapy at enabling people with a diagnosis of psychosis, living in the community, to improve the participation in their activities of everyday life; a feasibility study.

Researcher/chief investigator: Joanne Inman

Participant's Statement:

1. I confirm that I have read and understand the POINTER Study Occupational Therapist Information Sheet, dated:
   I have had the opportunity to consider the information ask questions and they have been answered satisfactory. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason, without my employment or legal rights being affected. ☐
3. I understand the researcher has a legal duty of care to report any concerns regarding my professional practice. ☐
4. I give my permission to use quotes and I understand that these will be anonymised. ☐
5. I agree to take part in the above Study ☐

----------	----------	----------
Name of participant	Date	Signature
----------	----------	----------
Name of the person taking consent	Date	Signature

When completed; 1 for participant and 1 for researcher site file

POINTER Study Occupational Therapist Focus Group, Consent Form.

Joanne Inman
North Barn,
Pathfinder Drive
Lancaster, LA1 3JT
Tel: 01524 550568

Centre Number: Occupational Therapist Identification Number:

POINTER Study Occupational Therapist Focus Group, Consent Form

Study title: Effectiveness of occupational therapy at enabling people with a diagnosis of psychosis, living in the community, to improve the participation in their activities of everyday life; a feasibility study.

Researcher/chief investigator: Joanne Inman

Participant's Statement:

1. I confirm that I have read and understand the POINTER Study Occupational Therapist Information Sheet, dated:
   I have had the opportunity to consider the information ask questions and they have been answered satisfactory. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason, without my employment or legal rights being affected. ☐
3. I understand the researcher has a legal duty of care to report any concerns regarding my professional practice. ☐
4. I understand that the focus group will be audio recorded and that the contents of the tape will be kept confidential. ☐
5. I give my permission to use quotes and I understand that these will be anonymised. ☐
6. I agree to take part in the Occupational Therapist Focus Group ☐

----------	----------	----------
Name of participant	Date	Signature
----------	----------	----------
Name of the person taking consent	Date	Signature

When completed; 1 for participant and 1 for researcher site file

HEALTH PROFESSIONS WITH PLYMOUTH UNIVERSITY

Lancashire Care NHS
NHS Foundation Trust

POINTER Study Occupational Therapist Registration Form
CONFIDENTIAL

Occupational therapist identification number (to be added by the research administrator):

Name:	
Age:	
Sex:	
HCPC registration:	Yes/ No
Length of time as qualified occupational therapist:	
Agenda for change banding:	
Percentage of current caseload that provide occupational therapy:	
Team setting:	
Written consent to be a participant in the POINTER Study:	Yes/ No

Researcher name: Date:

HEALTH PROFESSIONS WITH PLYMOUTH UNIVERSITY

Lancashire Care NHS
NHS Foundation Trust

POINTER Study Log of Questions/ Queries and Resolutions

Question Number	Date	Occ Ther No:	Question/ Query	Resolution

HEALTH PROFESSIONS WITH PLYMOUTH UNIVERSITY

Lancashire Care NHS
NHS Foundation Trust

POINTER Study: Occupational Therapy Intervention Log

Record the occupational therapy in the participants clinical notes as per your normal practice and your NHS Trust guidelines.

Please complete this form after each occupational therapy intervention and email it to michelle.greatorex@lancashirecare.nhs.uk.

Section A : Contact details (mandatory for all contacts with the participant).

Participant Number:
Occupational Therapist Number:
Date of Contact:
Duration of Contact:
Location of Contact:

Section B: Occupational Therapy Key Activities (mandatory for all contacts with the participant).

Please tick nature of contact and all key activities completed with participant

✓/x	Nature of Contact
	Occupational therapy
	Other – Please specify and give reason

✓/x	Occupational Therapy Key Activities
Objective 1 – Assess occupational performance	
	1a - Assess the individuals occupational performance in the participation of their activities of everyday life.
	1b - Establish activities & occupations most meaningful to the individual / causing greatest dissatisfaction with occupational performance.
	1c - Measure the individuals perceived levels of occupational performance and

	satisfaction.
Objective 2 – Formulate occupational needs	
	2a - Describe the individuals occupational performance in the participation of their activities of everyday life.
	2b - Identify with the individual, potential barriers to optimum occupational performance.
	2c - Identify the individuals occupational performance abilities (strengths) which could be used to help minimise and/ or overcome barriers to participation of their activities of everyday life.
	2d - Discuss and agree occupational needs formulation with the individual (& carer as appropriate).
Objective 3 - Set occupational therapy goals	
	3a - Set occupational need goals collaboratively with the individual (& carer as appropriate).
	3b - Prioritise occupational needs goals most meaningful to the individual / causing the greatest dissatisfaction with occupational performance in the participation of their activities of everyday life.
Objective 4 – Plan occupational therapy interventions	
	4a - Discuss options & negotiate the occupational therapy treatment interventions collaboratively with the individual (& carer as appropriate).
	4b - Agree treatment interventions that are meaningful & tailored to the individuals abilities, set in their own environments and occurring in their activities of everyday life.
Objective 5 – Implement occupational therapy interventions	
	5 - Enable "make possible" for the individual to successfully participate in an activity / occupation meaningful to them.
	5a - Use activities / or occupations that have meaning for the individual.
	5b - Use activities / or occupations to maintain / increase the individuals skills & abilities.
	5c - Adapt / use new activities & occupations with the individual.
	5d - Adapt / use new environments that activities & occupations occur in for the individual.

	5e - Reflect & evaluate on-going progress in real time.
Objective 6 – Reassess occupational performance	
	6a - Re-assess the individual's occupational performance in the participation of their activities of everyday life.
	6b - Have conversations with the individual (& carer as appropriate) about progress with occupational performance in their participation of the activities of everyday life.
Objective 7 – Review occupational need goals	
	7a - Review occupational need goals collaboratively with the individual (& carer as appropriate).
	7b - Re-assess baseline outcome measurement.
Objective 8 – Discharge from occupational therapy	
	8a - Occupational needs have been met to a satisfactory level for the individual.
	8b - Individual is discharged from occupational therapy.

Section C: Participant Adherence to Occupational Therapy (mandatory for all contacts with the participant).

Please rate the participants adherence (extent participant's behaviours complies with the interventions agreed, (Persh and Page 2013) to today's Occupational Therapy.

0 = No adherence 10 = Full adherence

0	1	2	3	4	5	6	7	8	9	10

Section D: Other interventions provided (mandatory for all contacts). Record all other interventions provided since previous occupational therapy intervention.

Interventions	**How Many?**
Care Co-ordination	
Psychological Intervention	

Social Work	
Other (please specify)	
Other (please specify)	
Other (Please specify)	

Section E: Occupational Therapy Goals Set (record only once when goals are set with the participant).

Priority number	Date set	Occupational performance problem	Goal description
1.			
2.			
3.			
4.			
5.			

Section F: Occupational Therapy Outcome Measure Scores (record at the beginning of Occupational Therapy and at completion or six months, by transferring scores from COPM Form**).**

COPM	Assessment (1):		Reassessment (2):	
Occupational Performance Problems:	**Performance 1**	**Satisfaction 1**	**Performance 2**	**Satisfaction 2**
1._____				
2._____				
3._____				
4._____				
5._____				

SCORING:

Total score = Total performance or satisfaction scores / Number Of problems (1-5)

PERFORMANCE SCORE 1	SATISFACTION SCORE 1	PERFORMANCE SCORE 2	SATISFACTION SCORE 2
=	=	=	=

COMPUTING CHANGE SCORES

CHANGE IN PERFORMANCE = Performance Score 2 ____ - Performance Score 1 ____ = ____

CHANGE IN SATISFACTION = Satisfaction Score 2 ____ - Satisfaction Score 1 ____ = ____

Section G: Record of overall Occupational Therapy effectiveness (record only at the completion of Occupational Therapy or at six months)

How effective was the Occupational Therapy intervention at enabling the participant to improve the participation, in their activities of everyday life?

0 = Not successful 10 = Very successful

0	1	2	3	4	5	6	7	8	9	10

What factors facilitated the success of the Occupational Therapy intervention?

1. -
2. -
3. -
4. –

What factors hindered the success of the Occupational Therapy intervention?

1. -
2. -
3. -
4. –

Section H: Withdrawal from POINTER Study - record only if participant is withdrawing from the study

Reason for withdrawal

Appendix 14

POINTER Study: Occupational Therapy Recording Guidance

Record all occupational therapy interventions in the participants' clinical notes as per your normal practice for your NHS Trust. Start each entry titled by the occupational therapy objective you are working on e.g. Objective 2 Formulation of occupational needs

Complete the POINTER Study: Occupational Therapy Intervention Log (Appendix 11) after each POINTER occupational therapy intervention and email it to michelle.greatorex@lancashirecare.nhs.uk.

- Section A: Contact details (mandatory for all contacts).

- Section B: Occupational Therapy Key Activities (mandatory for all contacts). Tick all Key Activities completed.

- Section C: Participants Adherence to Occupational Therapy (mandatory for all contacts). Rate participant's adherence to Occupational Therapy.

- Section D: Other Interventions Provided (mandatory for all contacts). Record all other interventions provided since previous occupational therapy intervention.

- Section E: Occupational Therapy Goals Set (record only once when the goals are set). Record up to five goals set with the participant.

- Section F: Occupational Therapy Outcome Measure Scores (record at the beginning and at completion or at six months of Occupational Therapy).

- Section G: Overall Occupational Therapy effectiveness (record at the completion or at six months of Occupational Therapy).

- Section H: Withdrawal from the POINTER Study (record only if the participant is withdrawing from the Study), record the reason.

HEALTH PROFESSIONS WITH PLYMOUTH UNIVERSITY

Lancashire Care NHS
NHS Foundation Trust

POINTER Study: Occupational Therapy Pathway Fidelity Checklist

Participant Number:

Occupational Therapist Number:

Date of Contact:

Objective/s being carried out:

Interventions Recorded		Evidence of POINTER Occupational Therapy Interventions In Case notes		
		✓	x	Notes
1a				
1b				
1c				
2a				
2b				
2c				
2d				
3a				
3b				
4a				
4b				
5				
5a				
5b				
5c				
5d				
5e				
6a				
6b				
7a				
7b				
8a				
8b				

Date:

Occupational therapy clinical specialist:

Appendix 14

POINTER Study Participant Questionnaire (to be completed after all outcome measures)

Participant identification number: Research assistant:

Date: Length of time taken to complete this questionnaire:

Question 1. Please tell us more about your experiences with your occupational therapist by answering the questions in Table 1.below:

Table 1. Satisfaction with occupational therapy					
	Experience of satisfaction (please tick that which most describes your experience)				
Experiences with my occupational therapist	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
My occupational therapist was friendly and approachable.					
My occupational therapist was respectful & my opinion mattered.					
My occupational therapist asked me appropriate questions about my activities and occupations.					
My occupational therapist listened to what activities and occupations are important to me.					
My occupational therapist helped me to identify what was helping and hindering me with participating in my activities of daily life.					
I set my goals with my occupational therapist.					
I discussed with my occupational therapist about how I wanted my occupational therapy to be provided.					
Occupational therapy made it possible for me to participate more in the activities and occupations that are meaningful to me.					
I talked to my occupational therapist about my progress with participating more in my activities of daily life.					
I reviewed my goals with my occupational therapist.					
I am more satisfied with my participation in the activities of daily life most meaningful to me.					

Question 2. How much did you stick to your occupational therapy plan?

Please rate how much you managed to stick to your occupational therapy plan:

0= Did not stick to my plan 10= Completely stuck to my plan

0	1	2	3	4	5	6	7	8	9	10

Question 3 Factors and hurdles to participating more in the activities of daily life most meaningful to you

3.1. What was the biggest factor in enabling you to participate more in the activities of daily life most meaningful to you?

3.2 What was the biggest hurdle for you in participating more in the activities of daily life most meaningful to you?

Q4 Assessment/ outcome measures – Please rate your experiences of answering the assessment/ outcome measure questions before and after you received occupational therapy (see Table 4. below):

Table 4. Satisfaction with the assessment/ outcome measures					
	Experience of satisfaction (please tick that which most describes your experience)				
Experiences of the assessment/ outcome measures	Very satisfied	Satisfied	Neither	Dissatisfied	Very dissatisfied
Time they took to complete					
Relevance of the questions					

Thank you for taking the time to complete this and for being part of the Study, Best wishes, Joanne Inman, Researcher

Appendix 15

POINTER Study Occupational Therapist Focus Group

Conversation guide *(these questions are written as a guide and although all questions will be used in the Focus Group, the purpose is to facilitate a conversation and therefore they are not exhaustive).*

Introduction and context setting Thank you for coming today and being part of this conversation, we want to hear and learn from your experiences about providing occupational therapy as part of the POINTER Study. This will help us to explore how feasible it is to carry out a pragmatic randomised controlled trial in the future.

Question 1. What were your experiences of following the occupational therapy pathway?

Question 2. In what situations was the occupational therapy pathway unable to be followed?

Question 3. What were your experiences of completing and submitting the POINTER Study Intervention Log?

Question 4. What were your experiences of participants' adherence to occupational therapy?

Question 5. How did occupational therapy enable the participants to participate in their activities of everyday life?

Question 6. Is there anything else that you think is really important to share and learn from, that you have not already had the chance to talk about?

Sum up and close Thank you for coming today and being part of the conversation about providing occupational therapy in the POINTER Study.

Appendix 16

Intervention schedule:
Occupational Therapy for people with psychotic conditions in community settings
Version 1.2004

Occupational therapy (green) & Generic (purple) components within each stage of the OT process
Obligatory and Optional*

The occupational therapist:

Referral acceptance	C1	**Decides** if the referral meets any locally agreed referral criteria for occupational therapy service (for example: HONOS areas 5,10 &12).
	C2	**Decides** if the referral is appropriate for the service and communicates this to the referrer, client and colleagues in the wider team.
Information gathering	C3a	**Gathers** information from the client's case notes, carers, and members of teams (primary and/or secondary care) to include: • Occupations and meaningful life roles. • Needs, strengths, goals previously identified by client. • Need for engagement strategies that are inclusive and non judgemental of those whose past experiences may make them reluctant to have contact with services. • The client's preferences for venue, people present when meeting new staff and cultural/language specific.
	C3b	**Gathers** information from the client's case notes, carers, and members of teams (primary and/or secondary care) to include: • Medical/ psychiatric history. • The client's current involvement with local services- consultants, care co-ordinators and other acute or community based staff. • Involvement with residential care staff or supported accommodation staff. • Other informal support networks and significant people (relatives, friends, neighbours). • History of risk and current risk assessment if available from team or colleagues (Mental Health Act 1983).
	C4	**Observes** the client (if the therapist already knows the client) and through the conservation gathers subjective evidence to add to above information.
Initial assessment	C5	**Initiates** contact – introduces self (via letter, phone or face to face contact) and explains purpose of the assessment.
	C6	**Gains** verbal or written informed consent to begin intervention (client and/or carer).
	C7	**Endeavours to build** rapport and trust with the client.
	C7a	**Carries out risk assessment.**
	C8	**Encourages** a client centred approach to therapeutic engagement, e.g. making relevant links with people already trusted by the client and persisting with offering opportunities for contact.
	C10	**Conducts** a functional / occupational performance assessment, i.e.: assessment of the client's competency in performing their routine roles and occupations in daily life, including self-care, productivity and/or leisure.
	C11	**Identifies** the following factors, which impact on the client's functional ability, occupational performance and health (using preferred model of practice)[1]. • Physical, cognitive, intra-personal and interpersonal skill domains. • The client's abilities and strengths, developmental level, current needs and limitations. • The client's feelings, attitudes, volition, interests and goals; the client's perception of their personal history, past experiences, cultural practices, political and cultural heritage. • The client's occupational role history, habituation, current work & housing status.

Initial assessment (continued)

C12 **Analyses** the client's environments to provide information about the causes of problems, explanations for behaviour or ideas for therapeutic adaptations. This includes the following:

- Objective observation and recording of who and what is there (content analysis).
- Appraisal of the effects of the environment on clients and their perceptions, behaviours and participation in occupations and activities (demand analysis).
- Identification of elements that need to be altered and the means by which this may be done (adaptive analysis).
- Tangible links being made between the client's occupational performance components (physical, mental, socio-cultural and spiritual); the environment in which they perform these tasks (physical, social, cultural) and how this impacts on ongoing purposeful activity and health outcomes.

C13 **Selects** and carries out appropriate methods of occupational therapy assessment from the following:

- Interacting informally with the client.
- Informal/Formal interview with clients and carers.
- Observing activity in the client's own living, working or social environments, or in the clinical setting.
- Setting the client specific tasks and observing responses.
- Standardised tests, e.g. AMPS, COPM, MOHO assessment tools.
- Engaging a client/s in group activities and observing responses.

C14 **Offers to share** with the client ownership of all assessment results and collaboratively decides whether the client would benefit from occupational therapy.

C15 **Records** assessment results.

C16 **Communicates** relevant results of the initial assessment to involved colleagues (with the client's consent), takes into account colleagues' findings.

C17 **Respects** the client's right to refuse further occupational therapy assessment or intervention and to withhold consent for assessment results to be shared with others. Records and respects these decisions, unless current Mental Health Act legislation contraindicates withholding this information on risk assessment grounds.

Reason for intervention/needs identification

C19 **Establishes** relationships with the client, carers and/or family (when feasible) in which mutual exploration and interpretation of perceived barriers occurs, along with desired outcomes of intervention and acknowledgement of what is realistically achievable.

C20 **Identifies** client's barriers to competent performance of adequate:

- Occupational balance – balancing work, leisure and self care routines.
- Occupational performance- developmental/social needs, social roles and environmental considerations.
- Activity participation- variety of activities (both individual and group) and frequency of engagement.
- Task performance. This includes the client's ability to accurately self assess skill levels and to adjust task demands to reflect this.
- Skills and abilities: in a wide range of social, intra-personal, domestic, work, leisure and self care areas.

Goal setting

C21 **Endeavours to facilitate** the client and/or carer's active participation in negotiating goal/action plans.

C22 **Collaboratively, expresses** the goals of intervention/s in terms of desired outcomes concerning occupational performance changes. These may be recorded as any of the following:

- Occupational targets to be met.
- Occupational aims to be achieved.
- Problems with occupation to be resolved.
- Occupational needs to be met.
- Adaptations to be made.
- Occupational or vocational plans to be completed.
- Maximising or maintenance of skills, abilities or potential.
- Coming to terms with deteriorating or restricted functioning.

Goal setting (continued)

C23 **Specifies** the direction of change as any of the following:
- Improvement in functional performance.
- Maintenance of function.
- Adaptation to level of disability or discomfort.
- Development/maturation of skills.
- Recovery of function.
- Maximising or maintenance of skills, abilities or potential.
- Coming to terms with deteriorating or restricted functioning.

C24 **Collaboratively, adjusts** goals to suit the client's needs and capacities at this particular point in time.

C25* **Collaboratively, identifies** with the clients when initial goals are unnecessary, unrealistic or cannot be entirely resolved.

C26 **Collaboratively, prioritises** occupational goals according to any of the following:
- Addressing the most basic or underlying problem.
- What issue/s the client perceives to be most important.
- Issue/s family or care staff see as overshadowing all other aspects of a client's occupational performance.
- Time and physical resources available to enable goal achievement.
- Addressing smaller goals on the way to achieving a longer term goal (graded activity program).
- Deal with most readily achievable goals first to build client trust and confidence.

C27 **Collaboratively, decides** what occupational goals to begin working on with the client. These initial goal/action plans maybe inclusive of:
- The client's tentative expression of what they want to happen.
- The therapists' synthesized perception of the client's abilities and needs.
- The therapist enabling the client to become more aware of his or her needs, to learn how to express these needs and wants and to make appropriate decisions.
- Strategies to facilitate ongoing engagement of the client with the intervention process.

C28 **Records** the goals that have been negotiated and agreed, including identification of the resources needed to carry out the intervention.

C29* **Records** goals that have not been collaboratively agreed to and outlines reasons for inability to address these goals, e.g. risk issues (Mental Health Act, 1983) professional knowledge or ethics constraints and lack of resources.

Action planning

C31 **Endeavours to facilitate** the client and/or carer's active participation in goal/action planning and encourages the client to select or agree the way in which the intervention is to be delivered.

C32 **Collaboratively, devises** a goal/action plan that is as follows:
- An intervention programme that is highly individualised and occupationally focused in response to all the information gathered and assessments completed.
- Outlines the approach to be utilised to achieve the goal/s, the environment/s, resource/s needed (as feasible), adaptations possible and the timelines available for completion/review of goal/s (activities, environmental adaptation, employed carers etc.).
- Includes interventions that may meet more than one goal or develop more than a single set of skills for the client.

C33 **Discusses** the goal/action plan with the treatment team as necessary; and in accordance with client confidentiality

C34 **Collaboratively, selects** activities (individual and/or group) that have the therapeutic potential to enable the client to achieve goals and complete action plans. Goals may include changes in client skills, awareness and environmental response (see goal setting).

Action planning (continued)	C35	**Selects** activities (individual and/or group) that have the potential to be graded, adapted sequenced or synthesized to meet changes in client's occupational competency and performance needs over time.
	C36	**Conducts** an activity analysis, i.e.: break down of an activity into its basic parts prior to grading and adapting activities to suit the client's occupational performance needs and skill development.
	C39*	**Plans** environmental adaptations, where possible, with an understanding of the dynamics of the setting (time pressures, changing circumstances, flexibility required) and how environments for intervention/s are perceived culturally.
	C40*	**Provides** assistive equipment and environmental modifications as required to facilitate functional skill development and graded, occupational performance success for the client.
	C42	**Records** the action plan stating the wishes of the client and/or carer, as well as the therapist's aims, plans and actions.
	C43	**Records** any risks in decisions made and actions taken; and the justification for each risk.
	C44	**Works** collaboratively with the client (and if appropriate the carer) in order to negotiate and share the control of the intervention process.
Action	C45	**Endeavours to work collaboratively with the care coordinator** and the treatment team in order to complete client centred interventions and achieve goals.
	C46	**Engages** the client, where feasible in planned activities (group or individual) that have been analysed, selected, adapted, graded or sequenced to achieve therapeutic goals concerning functional change.
	C47	**Encourages** the client to initiate as many required task actions as possible, with actions by others only when necessary.
	C48a*	**Carries out** activities together with the client, if necessary to achieve client's expressed, occupational and/or functional goals.
	C48b*	**Facilitates groups** of various types (recreational, activity based, educational, developmental) in various group structures (closed, open, formal, informal) and appropriate to the client's expressed needs.
	C49*	**Plans** activities that the client will carry out, independent of the therapist's and/or others support, as part of a graded action plan.
	C50*	**Discusses** with the client how her or his thinking, feeling and behavioural responses may be influenced by their engagement in a selected occupational or functional activity (individual and/or group).
	C51*	**Reviews** with the client how thinking feeling and behavioural responses to activity engagement influence future motivation to participate in that occupational/functional activity.
	C52*	**Facilitates** competency in problem solving skills related to occupation.
	C53*	**Assists** the client, where necessary to develop strategies for managing psychotic symptoms, that the client may experience whilst performing planned occupational or functional activities within their usual environments. This may include components suggested above (from 34 – 40).
	C54*	**Collaboratively, adapts** the environment to incrementally increase or reduce the social, emotional, cognitive, perceptual or physical demands placed on the client. This enables the client to complete a given activity successfully, within a given timeframe.
	C55*	**Grades** and sequences activities to increase incrementally the skill demands placed on the client so that she/he continues to develop skill competency whilst overcoming previous occupational performance barriers.
	C56*	**Adapts** activities (individual and/or group), by changing the demands of an activity for a specific therapeutic purpose. Changes may be made to: • Tools, position of equipment, materials. • Speed of performance, repetition, specific movements, strength and resistance. • Sequence of tasks, simplicity or complexity, degree of choice. • Instructions, context, location, number of participants. • Time provided to complete given activities.

Action (continued)	C59*	**Teaches** the client specific skills by demonstration and explanation, as required.
	C60	**Provides** the client with feedback on their occupational or functional performance; validating and rewarding achievements, and reviewing the client's realistic self-appraisal abilities.
	C61*	Delegates components of action plan delivery to other people (support workers, assistants, carers). Ensures that direct teaching and supervision is provided to others, so that their efforts are focused on achieving client's chosen occupational goals or graded activity program objectives.
	C62	**Uses** self as a therapeutic tool, as necessary; role modelling behaviours, occupations and facilitating change via therapeutic techniques described above.
	C63	**Explores** with the client what the activity means to her/him. The therapist needs to be aware that they may ascribe different values and meanings to given activities that the client performs, based on cultural perceptions/biases.
	C64*	**Refers** clients to, or consults with, other service providers when additional knowledge, expertise, or input regarding the client is required (includes home support workers).
	C64a	**Responds to crises and risks,** acting to maintain safety and involving services as needed.
	C65	**Respects** the client's right to refuse treatment.
	C66	**Records** the process and results of the intervention, using the notes to ensure that the action plan is moving towards its goals.
	C67	**Records** risks involved in respecting the client's choices and the justification for decisions made.
Ongoing assessment and revision of action	C68	**Assesses** and evaluates the client's progress towards previously agreed goals, to make sure what is done is effective. This is done via: • Observing changes in occupational performance, at intervals, in comparison with baseline performance. • Asking the client if she/he feels progress has occurred. • Measuring goal attainment. • Specific assessments using standardised measures. • Assessing the impact of the physical and social environments in which the client lives and works. • Evaluating her/his own involvement with the client.
	C69	**Modifies** or changes interventions in collaboration with the client in response to the evaluation of assessment findings.
	C70	**Adapts** occupational therapy programmes being carried out by others than the therapist as necessary.
	C71	**Records** assessment results, outcomes, further action required, unmet needs of the client.
	C72	**Gives** timely feedback to the treatment team where possible, regarding the interventions provided to date.
Outcome measurement	C73	**Collaboratively, agrees** with the client realistic, desired outcomes, expressed as goals or indicators of desired changes. Outcomes should relate closely to the client's social, psychological, emotional and cultural needs and expected occupational performance targets.
	C75	**Collaboratively, measures** with the client change over time by: • Establishing a baseline from which to measure change, e.g. occupational performance changes, skill development. • Implementing occupational therapy for an agreed time period and repeating assessments at intervals throughout intervention period. • Comparing assessment results before and after intervention.
	C76	**Collaboratively, reviews** with the client the goals and if appropriate, revises desired functional or occupational outcomes.
	C77	**Records** the achievement of outcomes, inability to achieve outcomes and rationale for both.

End of intervention or discharge	C78	**Collaboratively, plans** discharge from occupational therapy services with the client and liases with care coordinator regarding client's future community needs.
	C79	**Assesses,** prior to discharge from occupational therapy, the client's current level of daily and community living skills, leisure or work; and attends to strategies for maintaining or improving those skills for the client. This may include liaison with colleagues, family members, vocational support services or transfer of care to another occupational therapist in another sector of health and social care services.
	C80	**Clarifies** the reason for discharge from occupational therapy, i.e. for someone in their own home environment, recognises that the client has achieved her/his goals and is able to maintain her/himself within home, workplace and/or wider community environments. • Maintenance of client's community living may be achieved via other agencies' support. • Recognition of a client's inability or lack of appropriate service resources available to achieve desired goals may also be necessary.
	C81	**Via discussions** tries to reach an agreement with the team, the client and carer on the optimal time for discharge.
	C82	**Writes** a short report on discharge for client's notes (or detailed report if required).
Review	C84	**Reviews** and evaluates the occupational therapy service to safeguard good standards of practice and future service development initiatives.
	C85	**Carries** out self-appraisal and reflection.
	C86	**Undertakes** supervision and peer review.
	C87	**Elicits** client feedback via discussion, evaluation forms or a consumer questionnaire.
	C88	**Participates as required** in audits (in line with national and organisational standards for delivery of care).

OT Approach and models

The intervention of occupational therapy is delivered using the client centred occupational therapy approach.

This is based on client centred practice with a focus on how clients can perform their chosen occupations, within physical and social environments (see the definition below from Sumsion 2000). Once client centeredness has been established, the OT may select a particular model in order to deliver interventions that suit the individual client. The OT is not limited to only one model of practice and this allows for flexibility in addressing clients' needs.

> "Client centred occupational therapy is a partnership between the client and the therapist that empowers the client to engage in functional performance and fulfil his or her occupational roles in a variety of environments. The client participates actively in negotiating goals which are given priority and are at the centre of assessment, intervention and evaluation. Throughout the process the therapist listens to and respects the client's values, adapts the interventions to meet the client's needs and enables the client to make informed decisions." (Sumsion T. 2000 A Revised Occupational Therapy Definition of Client-Centred Practice: British journal of Occupational therapy, 63(7): 304-309)

Length of intervention

The intervention is delivered for up to 12 months with a minimum period of 3 months. This has been suggested from an analysis of case records and the estimates given by the expert panel of occupational therapists.

Notes

The intervention schedule was developed in four stages.

1. Sarah Cook and Mel Birrell wrote statements on what an occupational therapist does, using text from 'Occupational therapy defined as a complex intervention' by Jennifer Creek (2003), published by the College of occupational therapists, London.
2. An expert panel of twenty occupational therapists were consulted using the Delphi method. They rated each component and commented on the wording. It was then decided which components were specific to occupational therapy and which were generic to mental health work.
3. The section on 'action' was discussed with occupational therapists attending a seminar during the annual conference of the Association of Occupational Therapists and Mental Health.
4. The researchers consulted the occupational therapists that were preparing to use this schedule in a randomised controlled trial. Together they selected which components were obligatory for all clients and which were optional depending on the client's needs and environment.

During this process several of the original components were rejected or subsumed into other components. The following components are therefore not included in this schedule; 4, 9, 18, 30, 37, 38, 41, 57, 58, 74 & 83.

Acknowledgements

Thanks are given to Jennifer Creek, all the members of the expert panel and the occupational therapists involved in the trial (Sally Bramley, Nicky Watson and Steve McGrath).

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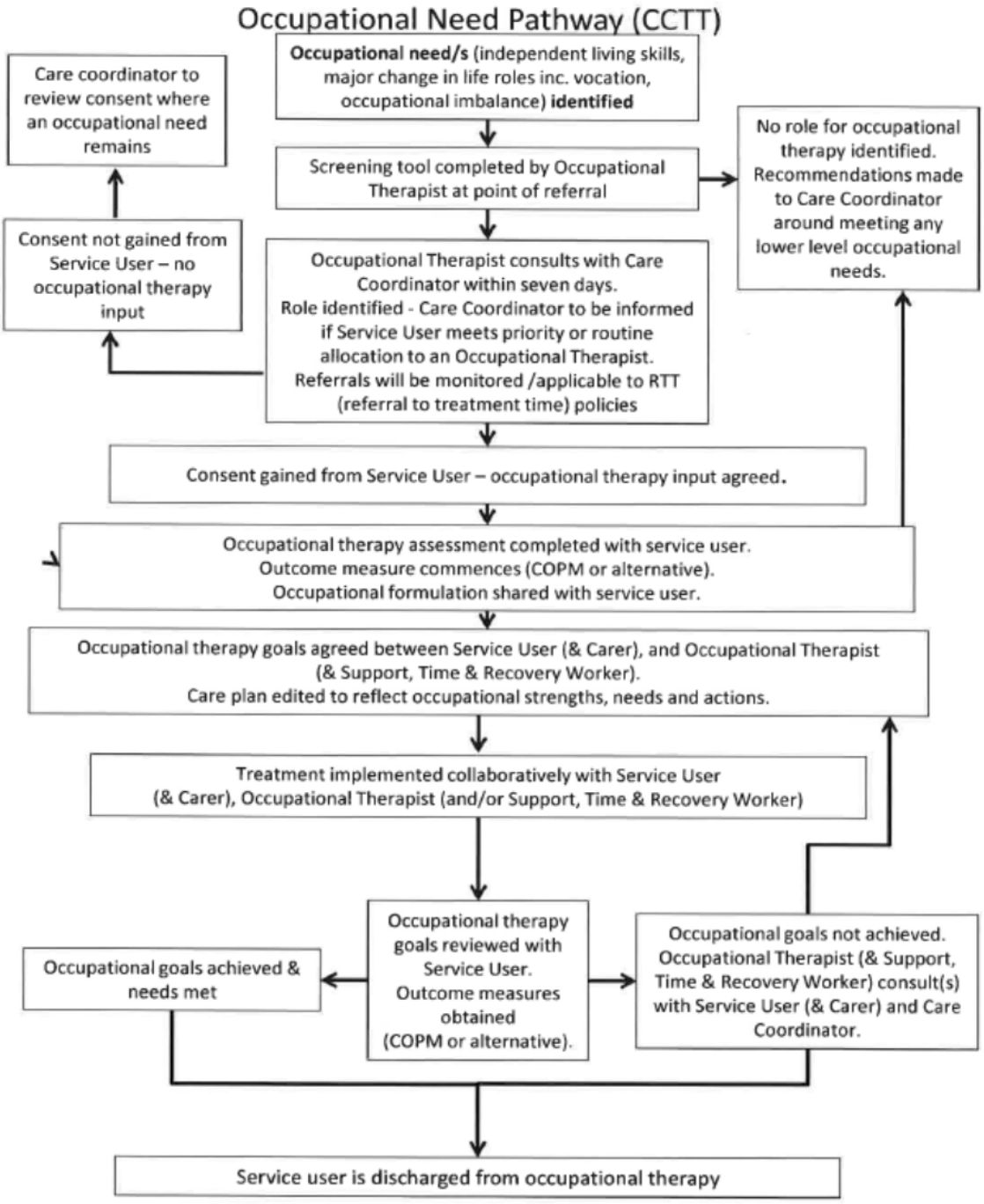
Appendix 17


Occupational Need Pathway (CCTT)
Occupational need/s (independent living skills, major change in life roles inc. vocation, occupational imbalance) identified
Care coordinator to review consent where an occupational need remains
Screening tool completed by Occupational Therapist at point of referral
No role for occupational therapy identified. Recommendations made to Care Coordinator around meeting any lower level occupational needs.
Consent not gained from Service User – no occupational therapy input
Occupational Therapist consults with Care Coordinator within seven days. Role identified - Care Coordinator to be informed if Service User meets priority or routine allocation to an Occupational Therapist. Referrals will be monitored /applicable to RTT (referral to treatment time) policies
Consent gained from Service User – occupational therapy input agreed.
Occupational therapy assessment completed with service user. Outcome measure commences (COPM or alternative). Occupational formulation shared with service user.
Occupational therapy goals agreed between Service User (& Carer), and Occupational Therapist (& Support, Time & Recovery Worker). Care plan edited to reflect occupational strengths, needs and actions.
Treatment implemented collaboratively with Service User (& Carer), Occupational Therapist (and/or Support, Time & Recovery Worker)
Occupational therapy goals reviewed with Service User. Outcome measures obtained (COPM or alternative).
Occupational goals achieved & needs met
Occupational goals not achieved. Occupational Therapist (& Support, Time & Recovery Worker) consult(s) with Service User (& Carer) and Care Coordinator.
Service user is discharged from occupational therapy

Appendix 18 Questions, queries and resolutions log

Question Number	Date	Centre number	Question/ Query	Resolution
30	28/01/15	02	Is it ok to have someone else present to translate to unsure the SU fully understands and can give informed consent to the study.	Yes, but please note this on the registration form.
31	29/01/15	02	It is going to be difficult to arrange face to face meetings between the OT, researcher and care coordinator. Is it ok if the OT and care coordinator meet without the research assistant	Yes as long as research assistant kept informed and discussions take place as needed.
32	30/01/15	01	There can be a delay for the service user to start occupational therapy because of the assessments that the research assistants need to do.	Unfortunately this is part of the challenge of doing research in practice. This can be minimized by liaising closely with the research assistant about prospective participants to help them plan their diaries.
33	30/01/15	01	On the participant information sheet it is confusing where it says 'verbal consent' and gives the option yes/ no. If the person verbally consents it only needs the date.	This will be amended on the paper work for the next study.
34	30/01/15	01	Where do I put the copy of the occupational need indicators form?	It was agreed that in Centre 1 this would be copied and pasted into the letters section as it contributes to the HoNos scoring and also if the participant is receiving occupational therapy in that team it is part of their care notes.
35	30/01/15	01	Is it okay to give the care co-ordinator a copy of the participant information sheet to take out to discuss with the potential participant prior to the occupational therapist contacting them about study.	Yes.

36	04/02/15	01	I have a referral for a service user who has a diagnosis of parkinsons and a diagnosis of treatment resistant schizophrenia. Does this person fir the inclusion criteria for the Study?	No because organic brain disorder is one of the exclusion criteria. Essentially we are trying to find out how occupational therapy (cause and independent variable) is able to (effect) participation in activities of daily life for people with a diagnosis of psychosis (dependent variable). The more we add in other significant diagnosis such as organic brain disorders the more variables we are adding in that might affect our conclusions about how occupational therapy effects participation in activities of daily life for people with a diagnosis of psychosis.
37	04/02/15	01	Can service users who are receiving a life-skills group be included in the POINTER Study?	Although these service users have been assessed as having occupational need and requiring occupational therapy, they would not be appropriate for the POINTER Study because the delivery technique in the POINTER Study is tailored and the delivery mode is face to face and 1:1. Although a group delivery technique does include tailoring for individual need, it is also a prescriptive approach from its very nature of being a group. And although the delivery mode is face to face, it is not completely 1:1 delivery mode.
38	30/01/15	02	Does the indicators form & letter go on ECR too as per usual processes?	Yes

39	30/01/15	02	Which of the letters do I replace with my own details? Is it the Pointer Study information letter?	No, the information letter contains information about the research study itself – Joanne's details need to be left on this one. It is the invitation letter that that has the grey bit on that you have to change – including the address details at the top.
40	03/02/15	Research Assistant	I have completed 3 of the 4 questionnaires for the first lady in the process of being recruited. I have yet to complete the time use survey and although we had a date booked in, her son is not well and she has asked to delay. **Is there a limited time frame between the research assistant visits?**	There isn't a set time between assessments, I would say monitor it – are we talking weeks or months?
41	06/02/15	Research assistant	How do we explain the relevance of the time use survey to service users and address any concerns regarding the personal nature of some questions	**Enabling participants to understand the relevance of the Time Use Survey:** Concerns about being able to make the relevance of this survey clear to participants, especially the section which asks very personal information about employment – taking into consideration these service users are experiencing psychotic symptoms and could become paranoid. Is there anything we could say to explain the rationale for this? **Joanne's advice:** You could explain to participants that the essence of the outcome measures are to find out about how the participants are spending their time in activities and how much these change over the period of having occupational therapy, that's the sole reason we are asking about them and they will only be used for the purpose of the Study and not shared elsewhere.

Appendix 19

Open coded	Sub-category	Generic category	Main Category
1.1 Documentation prior to study; not capture everything I was doing		Occupational therapy log reveals the intricacies of occupational therapy practice OTlogR	Doing occupational therapy research I practice (DOTRP)
1.1 Log – "oh yeah I was doing that"	Highlighted what I was doing	OTlogR	DOTRP
1.3 Log - highlighted what I was doing		OTlogR	DOTRP
1.13 Thinking processes behind intuition		OTlogR	DOTRP
2.14 Occupational therapy pathway smooth		OTLogR	
1.3 Talking about intervention helped recognise elements that I was doing		OTlogR	DOTRP
1.1 Insights about pathway through supervision	Insights about pathway through supervision	OTlogR	DOTRP
2.5 Intervention – starts and ends where it should	Intervention – starts and ends where it should	OTlogR	DOTRP
1.3 Working towards a particular theme at one time (e.g. assessment, goal setting or intervention)	Themes running through each stage of the intervention	OTlogR	DOTRP
1.1 Themes running through each stage of the intervention		OTlogR	DOTRP
1.1 Aspects of occupational therapy pathway carried out at same time	Aspects of occupational therapy pathway carried out in parallel	OTlogR	DOTRP
1.1 More parts of the schedule were happening than I		OTlogR	DOTRP

originally thought			
2.5 Do a bit more assessment, happens in real life		OTlogR	DOTRP
2.5 Intervention – to-ing and fro-ing in middle		OTlogR	DOTRP
2.17 Almost follow whole occupational therapy process in one session		OTlogR	DOTRP
1.1 Non-linear occupational therapy process		OTlogR	DOTRP
2.5 Life not linear		OTlogR	DOTRP
2.5 Fidelity checks – not sequential		OTlogR	DOTRP
2.3 Time to recruit people	Recruitment challenges	Recruitment and enrolment E&R	DOTRP
2.3 Not long enough		E&R	DOTRP
2.3 Not everyone met study criteria		E&R	DOTRP
2.3 Not everyone wanted to be involved		E&R	DOTRP
2.3Time of year affected recruitment		E&R	DOTRP
2.5 Someone met criteria and then diagnosis not correct		E&R	DOTRP
2.2 Uncomfortable if didn't want to be in study would be back on waiting list		E&R	DOTRP
1.18 Research assistants juggling clinical and research work		E&R	DOTRP
1.16 Recruited and then declined occupational therapy, no reason given		E&R	DOTRP
1.18 Slow recruitment, initial discussion, agreement and getting into the study	Recruitment needs to be 'quick and slick'	E&R	DOTRP
1.18 felt like pausing therapy		E&R	DOTRP
1.18 loss of momentum and engagement		E&R	DOTRP
1.18 recruitment needs to be quick and slick		E&R	DOTRP
1.18 delay from verbal consent to research assistant enrolment visit		E&R	DOTRP

2.1 Smooth screening assessment	Making enrolment even more successful	E&R	Doing occupational therapy research in practice (DOTRP)
2.1 Enrolment stage difficult		E&R	
2.1 Some enrolment not further than phone call		E&R	DOTRP
2.1 Difficult contacting client around study on telephone		E&R	DOTRP
2.1 Flexibility to contact by phone or face to face		E&R	DOTRP
2.1 Telephone saves time		E&R	DOTRP
2.1 Face to face enrolment would be beneficial		E&R	DOTRP
2.1 Face to face might improve enrolment		E&R	DOTRP
2.2 Enrolment – joint visit care coordinator?		E&R	DOTRP
2.2 Does it have to be OT having enrolment conversation		E&R	DOTRP
2.2 Research assistant initial enrolment conversation?		E&R	DOTRP
2.3 Care coordinator could have enrolment conversation		E&R	DOTRP
2.3 Depends on care coordinator		E&R	DOTRP
2.2 Easier to be detached from assessment	Being a research assistant who happens to be an occupational therapist	E&R	DOTRP
2.2 Face to face enrolment – see in service so not assess their environment		E&R	DOTRP
2.1 Careful not to do assessment 2.1 Clear about role		E&R	DOTRP
2.4 Balance out managing caseload and picking people up for study	Balancing managing caseload and picking people up for study	Balancing research and practice (BRP)	DOTRP
2.4 May be other non-study priority case		BRP	DOTRP
2.4 Six service users over six months		BRP	DOTRP
2.4 More occupational therapists and less service users each		BRP	DOTRP

2.4 More occupational therapists or more teams to draw from		BRP	DOTRP
2.4 Time for recruitment was a limiter		BRP	DOTRP
2.4 Future: stagger interventions		BRP	DOTRP
1.18 Future: more time to recruit		BRP	DOTRP
1.18 Future: extended period of progressing people into the study		BRP	DOTRP
1.18 Future: rolling approach to recruitment		BRP	DOTRP
2.4 Length of intervention	Optimum length of intervention	BRP	DOTRP
2.4 Six months ample		BRP	DOTRP
2.10 Timescale of intervention may have impacted negatively on outcomes		BRP	DOTRP
2.10 Six months intervention plenty for some and others are just getting going		BRP	DOTRP
2.14 Capture more improvement 9 or 12 months		BRP	DOTRP
1.3Doing more than one thing, wearing more than one hat 1.3 Being care co-ordinator drawn into other elements	Being care co-ordinator drawn into other elements	BRP	DOTRP
2.11I was writing up and ticking the log at same time	Time constraints can make detailed write ups difficult	BRP	DPTRP
2.11 Future: More time allowance for recording log		BRP	DOTRP
2.11 Sometimes treatment of more people to detriment of writing up		BRP	DOTRP
2.11 Time constraints can make detailed write ups difficult		BRP	DOTRP
2.11Log and case note write take time		BRP	DOTRP
2.11 Difficult to quantify write up time needed due to distractions		BRP	DOTRP

2.10 Helped meeting and talking with other occupational therapists in the study	Peer supervision	BRP	DOTRP
2.14 Useful conversations with other occupational therapists			DOTRP
2.14 Learning from each other			DOTRP
1.5 Log – structured and logical	Straight forward, structured and logical	Utility of log	DOTRP
1.5 Log – not too onerous			DOTRP
1.5 Log – not too time consuming			DOTRP
1.5 Log – straight forward			DOTRP
2.7 Log - a lot of it is what we do anyway	Identified and captured what actually delivered	Utility of log	Doing occupational therapy research in practice DOTRP
2.7 Log - identifies what actually delivered		Utility of log	DOTRP
1.5 Log – could pick out what I had done clinically with that person		Utility of log	DOTRP
1.5 Log – captured clinical entry		Utility of log	DOTRP
1.5 Log – captured what I was doing with individuals at that time.		Utility of log	DOTRP
1.5 Log – nothing I couldn't record		Utility of log	DOTRP
2.12 I wish I had practiced doing the logs	Getting the logs completed accurately	Utility of log	DOTRP
2.12 Log practice and feedback prior to study		Utility of log	DOTRP
2.7 Log – felt hard to do in specified order		Utility of log	DOTRP
2.7 Log numbered – feel like need to follow order		Utility of log	DOTRP
2.7 Log - worried might mess it up, not in order of pathway		Utility of log	DOTRP
1.5 Log – I got better at recognising what was occurring		Utility of log	DOTRP

2.7 Log - makes an impact on your practice	Enhanced practice and clinical note writing	Utility of log	DOTRP
2.7 Log – made think about what I was writing		Utility of log	DOTRP
2.7 Log – helps to re-focus what you have been doing		Utility of log	DOTRP
2.7 Log – can enhance practice generally		Utility of log	DOTRP
2.8 Log – could utilise to think before and after sessions		Utility of log	DOTRP
2.8 Log – supports reflective practice		Utility of log	DOTRP
2.8 Log and clinical notes relate		Utility of log	DOTRP
2.8 Log and clinical notes can be open to interpretation		Utility of log	DOTRP
2.13 Log almost like a template for writing entry		Utility of log	DOTRP
2.13 Future Log – could select from drop down list on ECR?		Utility of log	DOTRP
2.8 Helped matching up log and writing		Utility of log	DOTRP
2.8 I had to make sure I'd included writing everything		Utility of log	DOTRP
2.14 Fidelity check easy when corresponding log numbers used within written notes		Fidelity checks	DOTRP
2.8 Log objective 5 implementation, not sure completely capturing what doing service user does work outside session	Future considerations	Utility of log	DOTRP
2.8 Future: Space on log for comments regarding exceptions		Utility of log	DOTRP
2.8 Log – does it fully reflect what I did?		Utility of log	DOTRP
2.8 Log – it took me ages	Takes additional more time to complete	Utility of log	DOTRP
2.8 Log – felt didn't have enough time		Utility of log	DOTRP
2.8 Log – time pressures, so less good information		Utility of log	DOTRP
2.8 Future: Log – need to allow more time to complete		Utility of log	DOTRP
2.8 Log – not quick just because it's tick box		Utility of log	DOTRP
2.8 Spent extra time on documentation		Utility of log	DOTRP
1.3 Checking for non- occupational therapy contact – time consuming		Utility of log	DOTRP

1.14 Didn't want to repeat other outcome measures; too long, too many and done before	Completing outcome measures	Outcome measurement	DOTRP
1.14 Incentives may help complete outcome measures			DOTRP
1.18 Hard to get repeat outcome measures completed			DOTRP
1.18 Service user completion of outcome measures improved after request and explanation by Occupational therapist			DORP
1.5 Putting score/ number on progress – alien to service user	Scoring goals alien to some service users	Outcome measurement	DOTRP
2.9 Adherence ratings difficult – engagement in session though not done everything that set out to		Rating adherence	DOTRP
2.9 Adherence rated on how much carried forward what set in previous session			DOTRP
2.9 See them in next session and planned tasks didn't happen			DOTRP
2.9 Future: Two adherence ratings easier and clearer – (session and in-between)	Two adherence ratings easier and clearer		DOTRP
2.9 Motivation and engagement are not the same thing	Motivation and engagement are different things	Rating adherence	DOTRP
2.9 Adherence: whether motivated to engage			DOTRP
2.9 Adherence: whether managing to stick to planned session			DOTRP
2.9 Other factors can prevent person doing what set out to do, even when motivated			DOTRP
2.14 Adherence reflective of client groups engagement on caseload	Adherence reflective of client groups engagement on caseload	Rating adherence	DOTRP

Appendix 20

Factors that facilitated the success of the occupational therapy intervention; occupational therapists perspectives

Factors that facilitated success of the occupational therapy intervention
Development and establishment of a therapeutic relationship
Establishment of therapeutic relationship. Developed therapeutic relationship. Therapeutic relationship. Honest discussions. Open discussion. Therapeutic use of self (i.e. Employing humour and metaphor. Modelling acceptance and tolerance). 'Having trust in you.' You 'being reliable'.
Participant motivation, engagement and commitment
Service user commitment to intervention. Client's motivation to change. Good engagement from participant Service user's commitment to process. Client's motivation to change.
Engaging with an acceptance of differing realities
i.e. Avoiding argumentative debate regarding causal factors, diagnosis and the rationale for medical treatment. Boundary setting with service user
Working collaboratively with participant
Collaborative working. Collaborative working. Collaborative goal planning regarding identification of meaningful occupation
Effective goal setting
Clear goals. Realistic goals. Client centred goals. Identified specific goal.

Collaborative goal setting 'Knowing what I'm going to be doing.' Identification of meaningful achievable goals. Goal specific sessions.
Occupational need formulation
Developing an occupational formulation which enabled us to anticipate, accept and overcome barriers to participation. Client-centred formulation Identifying and discussing barriers.
Activation
The support has helped me do things for myself' (structure and routine). Activation of independent problem solving through coaching and environmental prompts.
Use of occupation meaningful to the participant
Occupation meaningful to participant. Identifying important factors to participant's life/spirituality. Past experience in occupation gave base line to build on, and increased opportunity to make achievements. The support to gain a bus pass, to attend snooker club regularly (without financial constraint).
Graded support and activities at participants level
Graded support, agreed collaboratively Went at service user's own pace. Course accessed at suitable level. Graded time specific challenges. Sensitive grading to create optimal degree of challenge to maintain motivation and progress. Ensuring sensitivity in weekly goal setting; to maintain a "just right" level of challenge.
Supportive environments
Environment for course used by other service users, eased participants concerns regarding stigma. Staff at the community centre, were supportive and non-judgemental; made participant feel at ease attending. Working effectively with the "human environment" (i.e. Engaging both service user and parents; as the permission and participation of family carers was central to

enabling the service user. Carer engagement in sessions.
Positive re-enforcement
Reflective discussion, especially on strengths and coping strategies. Positive reinforcement from therapist. Course provided certificate after each session providing a sense of achievement.
Close liaison and working with care co-ordinator
Close liaison with care coordinator, discussing behaviours & boundaries Close liaison & working with Care coordinator
Appointment/ intervention structure
Regular appointments. Weekly contact Length of contact (1hr) Time available for occupational therapist to carry out intervention on weekly basis in order to graded tasks appropriately.

Appendix 21

Factors that hindered the success of the occupational therapy intervention; occupational therapists perspectives

Factors that hindered the success of the occupational therapy intervention
Environmental: social support
Initial reticence from parents/carers. Chronicity of the habitual patterns of behaviour between family members. Limited social support outside of services. Limited ambitions and expectations of carers. Changes in staff within the housing project
Environmental: physical
Environmental factors – location and resources.
Finances
Financial restrictions. Financial restrictions. Financial factors impacting on mood (parents will)
Participant factors: physical health
Physical health. Physical health issues. Service user's physical health Commenced Clozapine which required monitoring and caused some drowsiness.
Participant factors: mental health
Motivation (negative symptoms). Motivation. Low motivation Insight. Level of motivation to change. Desire to change. Self focus on illness when experiencing changes in emotion. Service user's cognitions
Participant factors: historical trauma
Participant factors: attitudes/ beliefs
Negative self-belief. Limited ambitions and expectations of service user.
Participant factors: social
Social stressors. Social factors. estrangement from family (mother visiting locally during time period- no contact) Personal anniversaries: Eid; enforced marriage.

Social factors within the family.
Participant factors: established routines
Rigidity in routine, difficulty with spontaneity. Well established routines. Well established familial roles/routines. Overwhelming task
Participant factors: recent negative life experiences
Recent bereavement Loss of support from deceased girlfriend
Risk: had to go with support time and recovery worker because of risk.
Timeframe of study: because of Clozapine had a break in therapy.
Delay in CBT: to support him to work on cognitions alongside occupational therapy intervention.
Conflict of roles: Care coordination responsibilities resulted in an obligation to seek to renew and reinforce restrictive CTO conditions and to challenge some oppositional behaviour with regard to the legally mandated medical treatments.
Securing MDT support to maintain clarity of OT role and purpose: in relation to the competing needs and agendas.
Increased administrative burden of CPA and OT paperwork.