

**Occupational therapy and psychosis: POINTER feasibility study for a pragmatic clinical trial**

Word count: 4975

1 **Occupational therapy and psychosis: POINTER feasibility study for a**  
2 **pragmatic clinical trial**

3 **Introduction:** The dearth of clinical trials of individualised occupational therapy with  
4 people with a diagnosis of psychosis limits the evidence base globally for occupational  
5 therapy practice. This study evaluated the feasibility of conducting a pragmatic clinical  
6 trial.

7 **Method:** Mixed methods design using a pragmatic perspective; two-centre, one group  
8 pretest-posttest study at six months. POINTER Occupational Intervention  
9 Specification captured routine individualised occupational therapy. Process evaluation  
10 included recruitment, retention, intervention delivery, fidelity, adherence and outcome  
11 measurement. Primary outcome was participation in activities of everyday life,  
12 measured by: Time Use Survey, Participation Scale and Utrecht Scale for Evaluation  
13 of Rehabilitation Participation. The Canadian Occupational Performance Measure  
14 measured self-reported experience of and satisfaction with occupational performance.  
15 The Short Form-36v2 Health Survey measured Health-related quality of life; a  
16 secondary outcome. Participants' experiences were explored using a questionnaire.  
17 Intervention providers' perspectives were investigated via the POINTER occupational  
18 intervention log and focus groups.

19 **Results:** Recruitment was (20/36) and drop-out 20% (4/20). Fidelity was 77% and  
20 adherence was good; POINTER had validity and utility. Outcome measurement was  
21 acceptable to participants, indicating increased participation in activities of everyday  
22 life.

23 **Conclusion:** A larger clinical trial is merited; recruitment processes need further  
24 exploration and outcome measurement needs refining.

25

## 26 **Introduction and background information**

27 Mental health is the largest cause of disability across European Union Countries; 27%  
28 of the adult population have experienced at least one of a series of mental disorders  
29 in the past year (WHO 2018). Psychosis is a general term for a class of mental health  
30 disorders, which includes the following descriptions; schizophrenia, schizoaffective  
31 disorder, schizophreniform disorder, delusional disorder and affective psychosis e.g.  
32 bipolar disorder or unipolar psychotic depression (NICE 2014). The experience of  
33 psychosis:

34 “...include[s] hearing voices (‘hallucinations’), believing things that others find  
35 strange (‘delusions’), speaking in a way that others find hard to follow (‘thought  
36 disorder’) and experiencing periods of confusion where you appear out of touch  
37 with reality (‘acute psychosis’)” (Cooke 2014, p.10).

38  
39 Disability for those experiencing psychosis—affects both peoples’ activity and  
40 participation in their daily lives (Krupa et al 2010)— it is associated with narrowing of  
41 occupations, relationships and the places that people go to (Brown 2011).

42  
43 Occupational therapy enables individuals to improve participation in their activities of  
44 everyday life; participation in everyday life is an international research priority for  
45 occupational therapy specifically (Mackenzie et al 2018) and as an outcome for early  
46 intervention in psychosis research generally (Renwick et al 2018). Participation has  
47 international importance; activity and participation are core components of the  
48 International Classification of Functioning Disability and Health (ICF) (WHO 2001).  
49 Nevertheless, conceptual clarity is lacking (Khetani and Coster 2007) making it  
50 problematic to research ‘participation’ as an outcome, without a clear definition. A  
51 systematic literature review and narrative synthesis focused on mental health,

52 developed a definition for this study: “Participation occurs when an individual is  
53 involved in activities, within the context of their life, which provides that person with a  
54 sense of engagement” (Bannigan et al 2016a).

55

## 56 **Systematic review and best evidence synthesis**

57 As part of a programme of research underpinning this study, a separate systematic  
58 review and best evidence synthesis was conducted of occupational therapy and  
59 participation in activities of everyday life for adults with a diagnosis of psychosis  
60 (Inman 2017). It identified four categories of occupational therapy interventions; life  
61 skills training (n=6), individualised client-centred (n=5), activity-based (n=4) and  
62 cognitive (n=3) (Inman 2017). Of the five individualised occupational therapy  
63 intervention effectiveness studies identified and critiqued (Mairs and Bradshaw 2004,  
64 Cook et al 2009, Edgelow and Krupa 2011, Katz and Keren 2011, Lindstrom et al  
65 2012,), only one had high methodological quality (Cook et al 2009). All were tailored  
66 to individual needs using a structured format, i.e.: Occupational Therapy Intervention  
67 Schedule (Cook et al 2009), Action Over Inertia (AOI) (Edgelow and Krupa 2011),  
68 Occupational Goals Intervention (OGI) (Katz and Keren 2011), Occupational Therapy  
69 Intervention Process Model (OTIPM) (Lindstrom et al 2012) and Manual of Case  
70 Formulation Approach (Mairs and Bradshaw 2004). Three studies delivered training  
71 in the intervention for those providing it; however, fidelity to the treatment interventions  
72 was measured in only two studies (Mairs and Bradshaw 2004, Cook et al 2009,).  
73 Adherence to treatment was measured in one study (Cook et al 2009). There was no  
74 consensus on how to measure participation as an outcome. It was concluded that  
75 there was no evidence for the effectiveness for individualised occupational therapy on  
76 participation in activities of everyday life or quality of life (Inman 2017). The dearth of  
77 clinical trials internationally of sufficiently high methodological quality was concerning.

78 One approach to begin to address this was to conduct feasibility studies to support  
79 future robust clinical trials. Feasibility studies are conducted before a main study to  
80 ensure the study implementation is practical, reducing threats to the validity of findings  
81 (Tickle-Degnen 2013).

82

83 A fundamental issue in the design of future clinical trials was how to achieve  
84 intervention descriptions in sufficient detail to enable replication and achieve  
85 international reporting standards for clinical trials (Hoffman et al 2014). This remains  
86 a concern for the occupational therapy profession globally. A Cochrane review  
87 critiqued occupational therapy delivered by specialists (occupational therapists)  
88 versus non-specialists for people with schizophrenia (Morris et al 2018). Identifying  
89 the need for further research to develop the evidence base and reduce uncertainties  
90 around the best way of delivering occupational therapy for people diagnosed with  
91 schizophrenia (Morris et al 2018). Despite extensive searching and consulting experts  
92 in the field, no pre-existing individualised occupational therapy intervention  
93 specification for individuals with a diagnosis of psychosis, living in the community, was  
94 identified that met international reporting requirements for use in clinical trials  
95 (Hoffman et al 2014). Subsequently, the Participation through Occupational  
96 INTervention Effectiveness Research Occupational Intervention Specification  
97 (POINTER) was developed for this purpose—separate to, and as part of, a programme  
98 of research to support this study—applying the methodology for developing,  
99 evaluating and reporting complex interventions (Medical Research Council 2008,  
100 Inman 2017). This was not a new occupational intervention, rather a documentation  
101 of routine best-practice, incorporating best available-evidence to enable it to be  
102 evaluated and replicated under robust research conditions.

103

104 The aim of the POINTER Study, was to assess the feasibility of conducting a  
105 pragmatic clinical trial of individualised occupational therapy for people with a  
106 diagnosis of psychosis and occupational need. Key objectives were to explore; the  
107 validity and utility of the POINTER; levels and methods of measuring fidelity and  
108 adherence; valid method of measuring participation, with utility and the indication of  
109 effect of occupational therapy.

110

## 111 **Method**

### 112 ***Research Design***

113 An exploratory two-centre, one group pretest-posttest feasibility study for a pragmatic  
114 clinical trial of individualised occupational therapy was conducted; investigating both  
115 participant and process outcomes. The perceptions of the study procedures, the  
116 intervention and its effect were explored from the participant and intervention providers  
117 perspectives (Sturkenboom et al 2012). A pragmatic perspective was adopted  
118 exploring routine practice, as this enables the results to be more applicable to  
119 clinicians' own circumstances (Hotopf et al 1999). The pragmatic-explanatory  
120 continuum indicator summary (PRECIS) was applied when making study design  
121 decisions (Thorpe et al 2009).

122

### 123 ***Ethics***

124 The Health Research Authority, National Research Ethics Service Committee North  
125 West – Lancaster (NRES Ethics reference XXXXXX) 2013, granted full ethical  
126 approval. Registration was made to the Research Registry (XXXXXXXX).

127

128 **Participants**

129 From January to March 2014 participants were recruited from two centres; a total of  
130 seven community mental health and psychosis teams, as per pragmatic principles to  
131 use normal settings (Thorpe et al 2009). This was a convenience sample of teams  
132 who were willing to participate in the study. Eligible participants were over 18 years,  
133 living in the community, with a primary diagnosis of psychosis (dual diagnosis was  
134 acceptable) and mild to very severe occupational/ functional needs. Individuals were  
135 excluded if they had an organic brain disorder or suspected organic cause to  
136 psychosis (e.g. dementia) and/ or a primary diagnosis of substance misuse. The aim  
137 was to recruit 64 participants, to achieve a sample size of 60 (30 participants from  
138 each centre).

139

140 **Enrolment process**

141 Participants for the study were identified through occupational therapy referral  
142 processes in practice, as per pragmatic principles (Thorpe et al 2009) by their care  
143 coordinator, who routinely assessed their capacity and applied this to study  
144 involvement. Occupational need was indicated by a score of two or more on question  
145 10 of the Health of the Nation Outcome Scale (HoNOS) (Cook et al 2009); HoNOS  
146 measures the health and social functioning of people with severe mental illness and  
147 specifically problems with activities of daily living (Royal College of Psychiatrists  
148 2013). Once participants gave consent to engage in occupational therapy, the study  
149 was explained, and an information sheet provided. Research assistants obtained  
150 written consent and performed baseline measurement.

151

152 **Intervention: POINTER**

153 The intervention and delivery details are described using the Template for Intervention  
154 Description and Replication (TIDieR) as per international reporting standards for  
155 clinical trials (Hoffmann et al 2014):

- 156 1. Brief name: POINTER.
- 157 2. Why: To improve participation in the activities of everyday life that were most  
158 meaningful to the participants.
- 159 3. What (materials): The Canadian Occupational Performance Measure (COPM) and  
160 a range of daily activities meaningful to the participants.
- 161 4. What (procedures): Intervention providers (occupational therapists) followed  
162 POINTER to carry out its eight objectives (1. Assess occupational performance; 2.  
163 Formulate occupational needs; 3. Set occupational need goals; 4. Plan  
164 occupational therapy interventions; 5. Implement occupational therapy  
165 interventions; 6. Re-assess occupational performance; 7. Review occupational  
166 need goals and 8. Discharge from occupational therapy) and associated key  
167 activities (e.g. Objective 7. has two key activities; 7a. Review occupational need  
168 goals collaboratively with the individual and 7b. Re-assess baseline outcome  
169 measurement) (Inman 2017).
- 170 5. Who provided: Occupational therapists employed to work with individuals with a  
171 diagnosis of psychosis were the intervention providers; all registered with the  
172 Health Care Professions Council (HCPC).
- 173 6. How: Mode of delivery was face to face and one to one.
- 174 7. Where: Participants own homes and communities.
- 175 8. When and how much: Intervention dosage was weekly - two-weekly for up to six  
176 months. Participants could receive other health and social care interventions  
177 (these were recorded).



178 9. Tailoring: The occupational intervention was tailored to each participant,  
179 collaboratively setting their unique occupational need goals and plans; expecting  
180 and permitting variation in delivery, frequency and sequencing of objectives and  
181 key activities.

182 10. Modifications (during the study): reported in results.

183 11. How well (Planned measurement of adherence and fidelity): Fidelity to the  
184 intervention was measured for the study duration, as a percentage rating based  
185 on details about what was provided in each session compared to the objectives  
186 and key activities in POINTER. All objectives and key activities must have been  
187 carried out with the participant, before the end of the six-month period to achieve  
188 full fidelity. Adherence, was measured using the intervention providers' ratings on  
189 a scale of 0-10, after each session (final rating was the mean rating score).  
190 Participants rated their level of adherence once at the end of therapy on a scale 0-  
191 10.

192 12. How well: (Actual intervention adherence and fidelity in study): reported in results.

193

#### 194 ***Intervention providers' enrolment, training and supervision***

195 All intervention providers were selected via a convenience sample, they volunteered  
196 to take part and provided written consent. All had existing clinical caseloads, new  
197 participants commenced occupational therapy when the intervention provider had  
198 caseload capacity to work with them, as per clinical practice and pragmatic trial  
199 principles (Thorpe et al 2009). They received a half day training session on the  
200 POINTER study protocol, all completed Good Clinical Practice (GCP) NIHR research  
201 online training, engaged in monthly professional supervision and were invited to  
202 participate in the focus groups.

203

204 ***Study outcome measurement***

205 Baseline participant demographic data measured was; age, gender, diagnosis, time  
206 since diagnosis, employment status, occupational need, previous experience of  
207 occupational therapy. To enable evaluation of intervention providers' characteristics,  
208 data was collected on their age, gender and length of time as a qualified occupational  
209 therapist.

210

211 ***Process outcome measurement***

212 Process evaluation was considered from the participants and intervention providers  
213 perspectives qualitatively focusing on recruitment, retention, intervention delivery and  
214 utility of the methods to measure adherence, fidelity and outcome measurement. A  
215 participant questionnaire and POINTER occupational intervention log—to capture the  
216 delivery of the intervention, nature of contact, location, duration, objectives and key  
217 activities, participant adherence, interventions provided by others, occupational goals,  
218 COPM outcome measure scores and overall effectiveness, enablers and barriers—  
219 were based on the structure used by Sturkenboom et al (2012). The participant  
220 questionnaire aimed to capture participants' experiences of the occupational  
221 intervention and being involved in the study; largely made up of closed questions to  
222 minimise participant burden. It was reviewed by service users through the CRN Mental  
223 Health FAST-R (Feasibility And Support to Timely recruitment for Research) Service,  
224 National Institute for Health Research (NIHR).

225

226 A fidelity checklist was created for POINTER; fidelity was supported and monitored  
227 during the study through monthly professional supervision and using the checklist.

228

229 A focus group intervention provider conversation guide was developed by the primary  
230 researcher to explore experiences of being involved in the study and how occupational  
231 therapy enabled participants to increase their participation in activities if everyday life.  
232 This was critiqued by the CRN Mental Health FAST-R Service, NIHR to support  
233 validity. At the end of the study the primary researcher facilitated a focus group in both  
234 centres.

235

### 236 ***Outcome measurement***

237 Part of the purpose of this feasibility study was to identify the primary outcome  
238 measure for a future pragmatic clinical trial, three measures of participation in activities  
239 of everyday life were utilised. The definition of participation created for this study was  
240 applied to review the content validity of different measures of participation relevant to  
241 mental health (Bannigan et al 2016a) and found there was no reliable and valid  
242 measure of the primary outcome of participation in activities of everyday life (Bannigan  
243 et al 2016b). Of the measures reviewed the Participation Scale (P-Scale) (Brakel  
244 2010) and the Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P)  
245 (Zee et al 2010) had the strongest face validity, utility and acceptability amongst  
246 service users. In such circumstances, the criterion validity can be tested, by examining  
247 the outcome measures relationship with a robust measure of the primary outcome or  
248 one of its constructs (Saks and Allsop 2007). 'Time use', i.e. an individual's  
249 involvement in activities, is a key construct of participation. Having a diagnosis of  
250 psychosis has been associated with low total time use in activity (Leufsatdius and  
251 Eklund 2008). Therefore, changes in 'time use' in this study would be expected to have  
252 a positive correlation with participation. 'Time use' has been measured using the UK

253 2000 Time Use Survey (TUS), developed by the Office for National Statistics to  
254 measure the amount of time spent by the United Kingdom population, on various  
255 activities and was designed, where possible to provide results comparable with other  
256 European studies (Short 2006). An adapted version of the UK 2000 TUS (Short 2006)  
257 was used in a study with individuals with a diagnosis of psychosis and no issues  
258 regarding the utility were identified (Fowler et al 2009). This was used as the primary  
259 outcome measure; the Fowler et al (2009) survey was not available so the UK 2000  
260 TUS (Short 2006) was adapted in a similar way. The same two summary measures  
261 were used: hours in 'Constructive Economic Activity' and hours in 'Structured Activity'  
262 per week (Fowler et al 2009).

263

264 The P-Scale is an interview-based scale measuring participation restriction, a score of  
265 12 and below is considered to be 'normal', higher scores indicate more severe  
266 restrictions (Brakel 2010). The USER-P is a questionnaire assessing three aspects of  
267 participation: frequency, experienced restrictions and satisfaction of 'vocational  
268 activity' and 'leisure and social activity' (Zee et al 2010). Higher USER-P total scores  
269 indicate higher levels of participation (Zee et al 2010).

270

271 The Short Form–Health Survey (SF-36 v2) was used to measure health-related  
272 Quality of Life; normative data is available for the healthy population of the United  
273 States (Maruish 2011). It measures eight domains of health-related quality of life  
274 (HRQOL) and self-evaluated transition (SET) which compares their health now to one  
275 year ago (Maruish 2011).

276

277 The COPM has utility in clinical research for individuals with a diagnosis of  
278 schizophrenia (Cresswell and Rugg 2003). It measures self-reported experience of  
279 occupational performance and satisfaction using a scale of 1-10, a change in rating of  
280 two points or more is considered to be clinically significant (Law et al 1998).

281

### 282 ***Data collection***

283 Baseline demographic data, including outcome measures were collected from  
284 participants prior to intervention commencement by research assistants. At completion  
285 of the intervention (or at six months) outcome measures and the participant  
286 questionnaire were completed with participants by the research assistants. All  
287 measures completed by the research assistants were timed to assess participant  
288 burden. All research assistants received full training. Intervention providers  
289 (occupational therapists) socio-demographic and work experience data, and consent  
290 were collected by the primary researcher.

291

### 292 ***Data analysis***

293 As a feasibility study the data analysis strategy used descriptive statistics, qualitative  
294 analysis and the compilation of basic administrative and physical infrastructure data  
295 (Tickle-Degnen 2013), this was triangulated to evaluate the study outcomes. The  
296 primary researcher conducted the analysis and this was peer reviewed by the second  
297 and third authors to increase trustworthiness. Descriptive statistics illustrated baseline  
298 characteristics of participants and intervention providers, changes in outcome  
299 measure scores, participant experiences and intervention delivery. No statistical  
300 testing was possible of the construct validity of the participation measures due to the

301 sample size. Qualitative evaluation of the focus group data was analysed using  
 302 content analysis (Elo and Kyngas 2008).

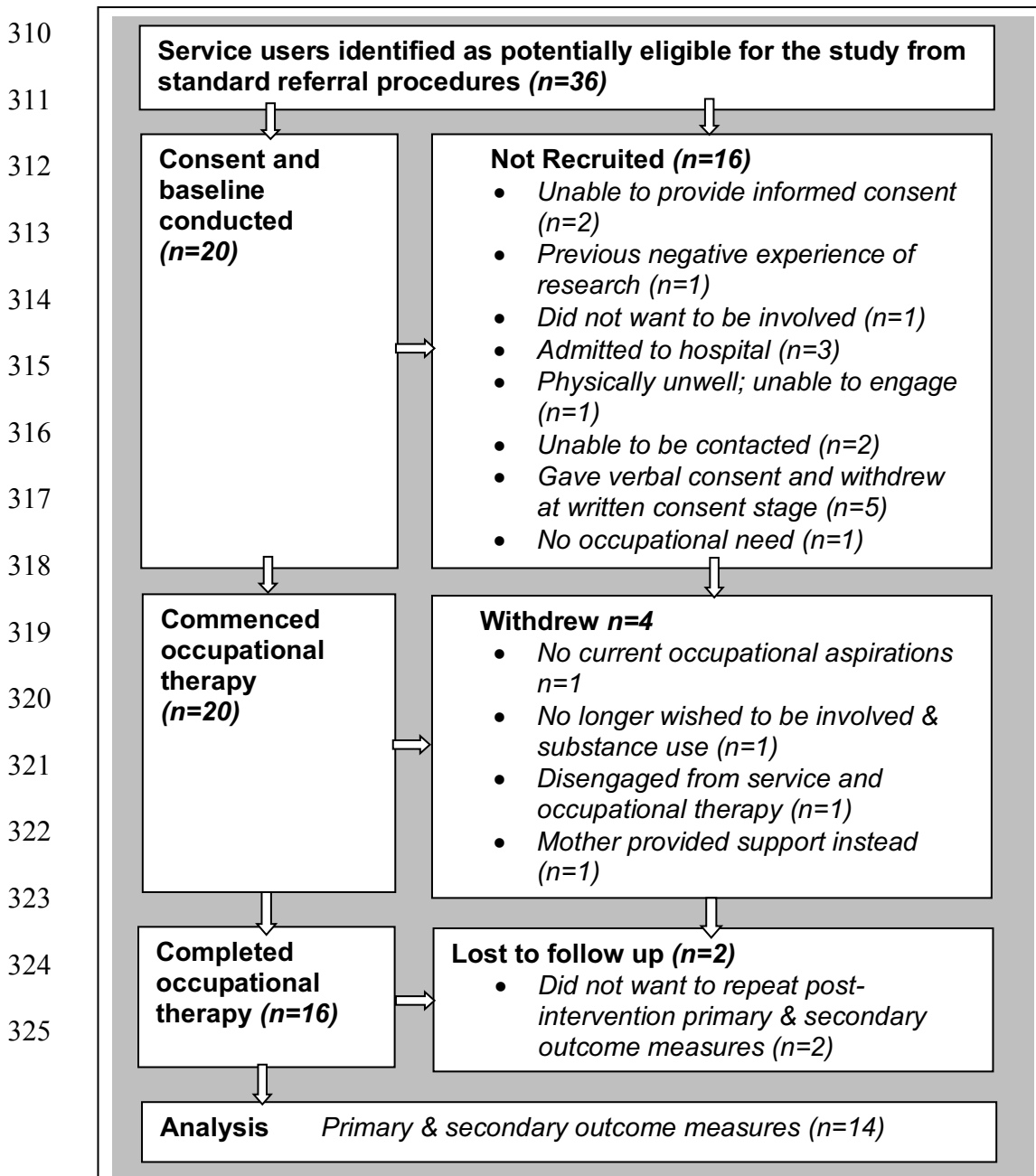
303

## 304 Results

### 305 Participants

306 From 36 potentially eligible service users, twenty were enrolled and 16 participants  
 307 completed therapy. The drop-out rate was 20% (n=4) (see Figure 1) and full data sets  
 308 were available for 14 participants.

309 Figure 1. Enrolment and participant flow diagram



326 There were differences between participants at baseline, in diagnosis and length of  
 327 time since diagnosis, between those who completed and withdrew (Table 1). Those  
 328 who withdrew also had lower time use scores at baseline.

329

330 Table 1. Participants' baseline characteristics

<b>Demographic, social and clinical characteristics</b>	<b>Participants (completed) (n=16)</b>	<b>Participants (with-drew) (n=4)</b>	<b>Total participants (n=20)</b>
Gender: Female	4 (25%)	1 (25%)	5 (25%)
Age (years): mean (SD)	43.06 (13.59)	46 (18.13)	43.65 (14.11)
Diagnosis: non-affective / affective psychosis)	13 (81.2%)/ 3 (18.8%)	1 (25%)/ 3 (75%)	14 (70%)/ 6 (30%)
Time since diagnosis (years): mean (SD)	13.13 (12.69)	10.25 (17.17)	12.55 (13.23)
Employed	1 (6.25%)	0	1 (5%)
Employment status: unemployed/ retired	14 (87.5%)/ 1 (6.25%)	3 (75%)/ 1 (25%)	17 (85%)/ 2 (10%)
HoNOS ( <i>problem with activities of daily living</i> )	16 (100 %)/	4 (100%)/	20 (1000%)/
Previous experience of occupational therapy	10 (62.5%)	2 (50%)	12 (60%)
Time use in constructive economic/ structured activity (hours per week): mean (SD)	6.94 (12.99)/ 13.2 (14.36)	6.2 (9.5)/ 9.98 (8.71)	6.79 (12.12)/ 12.35 (13.3)

331 Note. SD = standard deviation

332

333 **Process outcomes**

334 The process outcomes show the intervention provided used the relevant items (three  
335 - twelve) of the TIDieR checklist (Hoffmann et al 2014), inclusive of participants'  
336 (analysed from the participant questionnaire) and the intervention providers' (analysed  
337 from the focus groups and POINTER occupational intervention logs) experiences of  
338 the study.

339

#### 340 *Intervention provided*

341 3. Planned materials were used fully for 14 (87.5%) participants who completed the  
342 intervention.

343 4. The objectives and key activities in POINTER planned procedures were utilised by  
344 the intervention providers.

345 5. Seven intervention providers (occupational therapists) delivered the intervention,  
346 with a mean professional experience of 13.71 (7, SD) years, 45.71 (8.9) years of  
347 age, three were male and four were female.

348 6. The intervention was provided face to face and one to one.

349 7. One hundred and eighty-eight occupational intervention sessions were provided,  
350 144 (76.58%) were in participants' own homes, 33 (17.55%) in the community,  
351 seven (3.72%) participants own home and community, telephone, two (1.06%) and  
352 CMHT, two (1.06%).

353 8. The mean number of sessions per participant was 11.75 (6.58, SD), the duration  
354 was 19.06 (6.79, SD) weeks and the intensity was 65.15 (23.55, SD) minutes per  
355 session, for those who completed the intervention.

356 9. The permitted tailoring of the intervention was carried out; demonstrated in the  
357 intervention delivery details above.



358 10. POINTER captured 98% of the occupational therapy provided. Modifications made  
359 in the course of the study, included the provision of 'non-occupational therapy  
360 input'. Defined as interventions provided by occupational therapists for  
361 participants, which were not specifically occupational therapy e.g. delivery of  
362 medication or care co-ordination. This input was provided in 21 (12%) of the  
363 sessions and in discrete sessions on eight occasions.

364 11. Fidelity and adherence were measured as planned.

365 12. Fidelity and adherence monitoring occurred for 62% (n=117) of the sessions of  
366 those who completed therapy and there was 77% fidelity to the POINTER. The  
367 highest fidelity was achieved for 'assessing occupational performance' (94%) and  
368 'setting occupational therapy goals' (93.57%), and the lowest level of fidelity  
369 (53.13%) was achieved for 'discharge from occupational therapy'. Participants  
370 (n=14) were satisfied with their experience of each of the eight POINTER  
371 objectives (range 74% to 93%). The mean adherence rating from participants was  
372 6.54 and occupational therapists' mean was 7.68 (both on a 0-10 scale). 'Other  
373 interventions' from the multi-disciplinary team were also provided, as per usual  
374 care.

375

#### 376 *The Intervention providers' experiences*

377 The focus groups generated four overarching themes, one of these themes relates  
378 directly to this process evaluation and is reported here: 'Doing occupational therapy  
379 research in practice', see Table 2.

380

381 *Recruitment and enrolment:* Intervention providers discussed not enough time to  
382 recruit participants and not everyone met the inclusion criteria or wanted to be

383 Table 2. Qualitative process evaluation of delivery of the intervention

<b><i>Overarching theme 'Doing occupational therapy research in practice'</i></b>	
<b>General categories</b>	<b>Sub-categories</b>
<i>Recruitment and enrolment</i>	<ul style="list-style-type: none"> <li>• <i>Recruitment challenges</i></li> <li>• <i>Recruitment needs to be 'quick and slick'</i></li> <li>• <i>Making enrolment even more successful</i></li> <li>• <i>Being a research assistant who happens to be an occupational therapist</i></li> </ul>
<i>Utility of the occupational therapy log</i>	<ul style="list-style-type: none"> <li>• <i>Straight forward, structured and logical</i></li> <li>• <i>Takes additional more time to complete</i></li> <li>• <i>Identified and captured what actually delivered</i></li> <li>• <i>Getting the logs completed accurately</i></li> <li>• <i>Enhanced practice and clinical note writing</i></li> <li>• <i>Future considerations</i></li> </ul>
<i>Occupational therapy log revealed the intricacies of occupational therapy practice</i>	<ul style="list-style-type: none"> <li>• <i>Highlighted what I was doing</i></li> <li>• <i>Insights about the occupational therapy pathway through supervision</i></li> <li>• <i>Intervention – starts and ends where it should</i></li> <li>• <i>Themes running through each stage of the intervention</i></li> <li>• <i>Aspects of occupational therapy pathway carried out in parallel</i></li> </ul>
<i>Outcome measurement</i>	<ul style="list-style-type: none"> <li>• <i>Completing outcome measures</i></li> <li>• <i>Scoring goals alien to some service users</i></li> </ul>
<i>Rating adherence</i>	<ul style="list-style-type: none"> <li>• <i>Motivation and engagement are different things</i></li> <li>• <i>Two adherence ratings easier and clearer</i></li> <li>• <i>Adherence reflective of client groups engagement on caseload</i></li> </ul>
<i>Balancing research and practice</i>	<ul style="list-style-type: none"> <li>• <i>Balancing managing caseload and picking people up for study</i></li> <li>• <i>Optimum length of intervention</i></li> <li>• <i>Being care co-ordinator drawn into other elements</i></li> <li>• <i>Time constraints can make detailed write ups difficult</i></li> <li>• <i>Peer supervision</i></li> </ul>

384

385 involved. The research assistants also had clinical caseloads (separate to this study);  
386 identified as sometimes slowing the recruitment process. It was recognised  
387 recruitment needed to “be quick and slick and responsive” (OT3C1.18). Strategies for  
388 making enrolment even more successful were suggested including: having the initial  
389 occupational needs screening and conversation about the study either via the  
390 telephone or on the home visit with the care co-ordinator.

391

392 *Balancing research and practice:* The intervention providers spoke about ‘Balancing  
393 managing a caseload and picking up new participants for the study’. It was  
394 recommended to be more realistic to recruit one participant per month alongside  
395 existing caseloads, over a six-month period. The ‘Optimum length of the intervention’  
396 was debated, some were concerned the six-month time limit for the intervention may  
397 have negatively impacted outcomes; nevertheless, it was also recognised that, for  
398 some participants, six months was ample. ‘Peer supervision’ was deemed a useful  
399 mechanism for learning and support.

400

401 *Utility of the occupational intervention log:* Capturing and recording the occupational  
402 intervention was reported as “pretty straight forward to do” (OT1C1.3), and “it was kind  
403 of structured, it was logical, it was a concept I was familiar with” (OT3C1.2). It was  
404 consistently testified that the POINTER occupational intervention log captured “what  
405 you’ve actually delivered in that session” (OT4C2.2). However, it also took additional  
406 time to complete, more than just doing clinical notes. Getting the logs completed  
407 accurately required practice and some reported that they wished that they had  
408 practiced using them more before the study had begun.

409

410 *Occupational therapy log revealed the intricacies of occupational therapy practice:* The  
411 POINTER occupational intervention log highlighted what occupational therapists were  
412 doing and articulated the thinking processes underpinning what felt like their intuition.  
413 Described by one as: “It broadly starts off where it should do, and it definitely ends  
414 when it needs to, but in the middle then there’s lots of to-ing and fro-ing and going  
415 back to the beginning and doing a bit more of an assessment...which is what happens  
416 you know in real life” (OT4C2.5). It was acknowledged that aspects of POINTER were  
417 carried out in parallel and that the process was non-linear, just as life is not linear.  
418 Comments included: “More parts of the schedule were happening than I originally  
419 thought” (OT1C1.1). “You almost follow the whole occupational therapy process in one  
420 session” (OT2C2.17).

421

422 *Rating adherence:* One intervention provider commented “I think the adherence that  
423 we’re talking about is probably reflective of the client group that we are working with”  
424 (OT2C2.14). Adherence was expressed as being affected by many factors, motivation  
425 being key and it was questioned: “Should it be more around motivation to engage then  
426 rather than engagement?” (OT1C2.9). It was recommended that two adherence  
427 ratings would be easier and clearer: one for the actual intervention session and  
428 another for activities carried out as planned, in-between sessions.

429

430 *Outcome measurement procedure and processes:* There were challenges getting  
431 post-intervention outcome measures completed and it was advised that incentives for  
432 participants may help to improve this response. One described the experience of  
433 scoring goals with a participant: The “guy I was working with was very, you know, the  
434 whole idea of putting a number onto something was quite alien to him” (OT2C1.6). It

435 was highlighted that many participants responded more comfortably to setting small  
436 goals about their everyday living during and in-between face to face sessions.

437

438 With regards to participant burden 11 (79%) participants reported being either very  
439 satisfied (n=5, 36%) or satisfied (n=6, 43%) with the time to complete the outcome  
440 measures for the study. The mean time to complete the outcome measures (in  
441 minutes) were: TUS 22.47; SF-36v2 8.91; The P-Scale 10.13; USER-P 11.94.

442

#### 443 ***Outcome evaluation***

444 Outcome measure data demonstrated a generally positive direction of change with the  
445 primary outcome of participation in activities of daily life (see Table 3). Self-reported  
446 experience of occupational performance and satisfaction with occupational  
447 performance scores also indicated improvements.

448

449 In the health-related quality of life data; four health domains showed improvements  
450 and four indicated increased health burden. Self-evaluated transition (SET) in health  
451 in general improved, shown by pre-post intervention mean differences (3.07, 1.3SD)  
452 to (2.38, 1.55SD).

453

454 The majority of participants (n=10, 71%) were more satisfied with their participation in  
455 the activities of daily life most meaningful to them and that occupational therapy made  
456 it possible for them to participate more in activities and occupations that were  
457 meaningful to them. The occupational therapists mean subjective evaluation score for  
458 the effectiveness of POINTER provided was 6.36 (Scale of 0 = not successful – 10 =  
459 very successful).

460

461 Table 3. Results of primary outcome

<b>Outcomes (Measure)</b>	<b>Baseline/ Pre- intervention n=14 mean (SD)</b>	<b>Post- intervention n=14 mean (SD)</b>	<b>Pre-post mean difference</b>
Time use constructive economic/ structured activity, per week (TUS)	7.53 (13.83)/ 14.04 (15.07)	8.63 (14.4)/ 16.7 (21.82)	1.1/ 2.66
Participation restriction (P-Scale)	26.5 (6.05)	25.79(15.08)	-0.71
Participation restriction (USER-P)	13.86 (6.06)	17.21 (7.06)	3.35
Frequency of participation in: vocational/ leisure & social activity (USER-P)	1.36 (0.63)/ 12.57 (6.72)	1.71 (1.2)/ 11.21 (5.51)	0.35/ -1.36
Satisfaction with participation (USER-P)	16.93 (9.34)	17.5 (7.47)	0.57
Self-reported experience of occupational performance satisfaction (COPM)	3.81 (1.53)/ 2.7 (1.2)	6.39 (1.79)/ 6.49 (1.62)	2.58/ 3.79

462

463

464 No ancillary analysis was undertaken and no harms were reported from the  
465 intervention.

466

## 467 **Discussion**

468 This study demonstrates the value of feasibility studies prior to clinical trials to improve  
469 rigor and reporting. This study achieved an 80% retention rate, which is an acceptable  
470 sample size for an effectiveness study with short-term follow up (Steultjens et al 2002).  
471 However, fewer participants (n=20) were recruited than planned (n=64), this was not  
472 an issue in the pilot study by Cook et al (2009) and may be due to the pragmatic design  
473 of this study. This suggests planning more time and occupational therapists,  
474 accounting for the demands of occupational therapists' pre-existing caseloads to  
475 ensure recruitment targets are met. Equally the recruitment in this study could  
476 contribute to a power calculation for sample sizes in future studies. The baseline  
477 differences, between those who completed therapy and those who did not, suggest  
478 the POINTER may need to include actions to engage service users with low volition  
479 and consider how occupational therapists respond to this type of diagnosis. This will  
480 need to be monitored in future studies.

481

482 In contrast to the interventions identified in the systematic review (Inman 2017), all of  
483 the items in the TIDieR checklist (Hoffmann et al 2014) were captured and reported  
484 within this study, which is critical to achieving a study with high methodological quality  
485 (Steultjens et al 2002). POINTER captured 98% of the occupational therapy carried  
486 out, strengthening its validity as a description of individualised occupational therapy  
487 for people with a diagnosis of psychosis. Although the POINTER occupational

488 intervention log did take more time to complete than only delivering the intervention, it  
489 captured what was actually delivered.

490

491 This study achieved an overall fidelity level of 77%; above that achieved by  
492 Sturkenboom et al (2012). As well as being an acceptable level of fidelity it indicates  
493 the utility of the method used. The participants and the intervention providers'  
494 adherence ratings were relatively closely scored, suggesting the validity of the ratings  
495 and, therefore, the method used to measure. However, the intervention providers  
496 requested an additional adherence measure for in between sessions which will be  
497 considered in future studies.

498

499 This was a small sample, with-in group variability, and it was always recognised these  
500 results would not be generalisable, nevertheless the findings are promising. The  
501 majority of participants experienced occupational therapy making it possible for them  
502 to participate more in activities and occupations that were meaningful to them. The  
503 results have shown positive change scores from baseline to post-intervention on: Time  
504 Use, Self-reported Experience of Occupational Performance and Occupational  
505 Performance Satisfaction, Satisfaction with Participation, and Participation Restriction.  
506 In addition, the self-reported experience of occupational performance and satisfaction  
507 with occupational performance showed clinically significant improvements for those  
508 participants in the study and the pre-post intervention mean differences are  
509 encouraging. Participants also experienced better health in general (SET) at post-  
510 intervention. Participants continued to receive other routine community mental health  
511 non-occupational therapy interventions, as is common to pragmatic clinical trials;  
512 some changes could be argued to be attributed to these. All further indications that a



513 larger pragmatic clinical trial is merited. As this was a before-after feasibility study, no  
514 follow-up outcome assessments were carried out and this will be incorporated into the  
515 next study when testing effectiveness.

516

517 The TUS, USER-P, P-Scale and COPM were all found to be sensitive enough to detect  
518 change with this client group and created minimal burden on participants. Despite  
519 statistical analysis of the concurrent validity of the TUS and participation measures not  
520 being possible, the results from comparing the direction of change on the face of it,  
521 suggest the links are promising. Further refinement of the outcome measures is  
522 warranted, especially as there was no consensus on outcomes or measures in the  
523 systematic review.

524

#### 525 **Limitations**

526 Not achieving the planned sample size prevented further validity testing of the  
527 measures of participation. Even so, the sample was reasonable for a feasibility study  
528 and provided useful insights into recruitment issues and the burden on the intervention  
529 providers. This study prioritised engagement and minimising burden on participants,  
530 as guided by the pragmatic perspective. However, this approach has limitations; it  
531 reduces the depth of information generated about participants' experiences of being  
532 involved in the study and subsequently the process outcome learning.

533

534 Fowler et al (2009) adapted the TUS (Short 2006), this was not accessible and, whilst  
535 similar adaptations were made to the TUS (Short 2006), these may not have replicated  
536 those made by Fowler et al (2009). When analysing the SF-36v2 outcome measure  
537 data it became apparent that there were no norm-based scores for people with a

538 diagnosis of psychosis in the UK. The norms for the United States general population  
539 were utilised, which may have affected the validity of the results. In terms of next steps,  
540 a measure for health-related quality of life needs to be explored to include more  
541 diagnosis specific considerations.

542

### 543 **Conclusion**

544 Key uncertainties involved in designing a pragmatic clinical trial of individualised  
545 occupational therapy with people with a diagnosis of psychosis and occupational need  
546 were resolved. The fundamental issue of intervention reporting that conforms to the  
547 internationally recognised *TIDieR checklist* has been overcome; its use will strengthen  
548 the methodological quality of a future pragmatic clinical trial (Hoffmann et al 2014).  
549 The analysis of the study process outcome measures also highlighted how a future  
550 clinical trial could be bolstered with regards to recruitment, sample size and retention.  
551 The indication of effect of this early phase study shows promise; however, further  
552 validity testing of the outcome measures is required. Having addressed multiple  
553 research design uncertainties, alongside indicators of effectiveness from participants  
554 and outcome measure data, a larger pragmatic clinical trial is now warranted.

555

556 **Key findings:** The majority of participants with a diagnosis of psychosis experienced  
557 occupational therapy as enabling them to participate more in activities and  
558 occupations that were meaningful to them.

559

560 **What the study has added:** POINTER is a valid description of individualised  
561 occupational therapy, and has been shown to have good utility to support robust  
562 reporting of clinical effectiveness research.

563

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565 application of this research for any of the authors.

566

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