Occupational therapy for people with psychotic conditions in community settings: a pilot randomized controlled trial

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Abstract

Objectives: To investigate the effectiveness of a long established intervention, occupational therapy for people with psychotic conditions, and to inform future research designs.

Design: A pilot randomized controlled trial.

Setting: Two community mental health teams in a UK city.

Participants: Forty-four adults with schizophrenia or other psychotic conditions, eligible for enhanced care and having functional problems.

Interventions: Twelve months of individualised occupational therapy (OT) in community settings, as an adjunct to usual care and compared to treatment as usual (TAU). A two to one randomisation ratio was used to enable more people to receive OT.

Outcome measures: Social Functioning Scale (SFS), Scale for the Assessment of Negative Symptoms (SANS) and employment.

Results: Both groups' scores on SFS and SANS showed significant improvement over 12 months. For SFS, the OT group scores were: mean difference = 2.33, CI: 0.39 to 4.27, t = 1.525, P= 0.020 and the TAU group were: mean difference = 6.17, CI: 1.04 to 11.29, t = 2.65, P = 0.023. For SANS, OT group scores were: mean difference = -16.25, CI: -22.94 to -9.56, t = -4.99, P <0.001 and the TAU group: mean difference = -17.36, CI: -29.78 to -4.94, t = -3.12, P = 0.011. There were no differences between the two groups on any of the outcome measures. After 12 months the OT group showed clinically significant improvements that were not apparent in the control group. The OT group showed clinical improvement in 4 subscales of the SFS: relationships, independence performance, independence competence, and recreation. Out of 30 people receiving OT those with a clinical level of negative symptoms reduced from 18 (64%) to 13 (46%) P = 0.055.

Conclusion This pilot study suggested that individualised occupational therapy may contribute to recovery but more focus is recommended on people's cognitive abilities and employment.

Introduction

Further research is needed on what is effective in the rehabilitation of people with psychotic conditions. This client group mostly comprises people diagnosed with schizophrenia, but also includes people with schizoaffective disorders and those affected by bipolar disorder with psychotic symptoms (1). The international lifetime prevalence for schizophrenia has a median of 4 per 1000 people (1.6 – 12.1) with higher rates in developed countries (2). People with psychotic conditions tend to experience difficulties in social functioning, self care and cognitive function (3), residual negative symptoms (4) and high rates of unemployment and social exclusion (5). Cognitive deficits and negative symptoms such as impoverishment of thought (alogia), inability to initiate or sustain purposeful activities (avolition) and lack of energy (anergia) continue over time and contribute to long term disability (4).

There is no conclusive evidence that any specific therapy intervention improves social functioning and negative symptoms for people with psychotic conditions. Programmes using behavioural therapy techniques to reward target behaviours with tokens may have beneficial effects on negative symptoms but have been limited to long stay ward environments and not rehabilitation in the community (6). Morita therapy, which employs a psychotherapy based on eastern philosophy and engages people in constructive behaviours, has shown some early positive impact on negative symptoms and social functioning but only in hospital settings and lacks systematic investigation (7). Music therapy has been shown to have some beneficial but inconsistent effects on negative symptoms and social functioning (8). There is more promising evidence that cognitive remediation therapy or integrated treatment strategies may improve social functioning and reduce negative symptoms.[3;9] Regarding employment, the Individual Placement and Support model of supported employment has been found to be significantly more effective

than other strategies. However a systematic review of Individual Placement and Support found that only 34% of people with severe mental illness attained competitive employment at 12 months, suggesting that work remains a substantive challenge for many people (10).

The focus for this study was the effectiveness of the established practice of occupational therapy. Although evidence based practice generally validates novel treatments as more effective than older therapies (11), established therapies that are routinely delivered do merit investigation. Occupational therapy draws on the emerging discipline of occupational science, which asserts that engagement in meaningful and satisfying occupations contributes towards health and wellbeing, social inclusion, improved functioning and self respect.[12] Occupational therapy has contributed towards the treatment and rehabilitation of people with severe mental health problems since it emerged at the beginning of the 20th century in the USA[13] and became formally established with training standards in 1920.[14] There are currently approximately 11,000 occupational therapists practicing in primary and secondary mental health care in the UK, and this is replicated in several other countries[15],

There has been only suggestive evidence that mental health occupational therapy is effective for people with psychotic conditions. Three small single cohort studies reported that occupational therapy may be beneficial.[16-18] A UK study combining occupational therapy and care management for 37 people with psychosis in the sole care of their GP surgery showed improved scores on the Social Functioning Scale (SFS) with a mean difference of 6.9 (CI 4.2-9.5) $p<0.001$.[16] Another UK study of 12 sessions of life skills training for people with schizophrenia individualised to each client's goals and delivered by occupational therapists in the 13 participants' homes, showed a reduction in negative symptoms over time ($p = 0.059$) but a non-significant decrease in the group's mean SFS scores (109 to 104).[17] A study of occupational therapy plus supported employment for 52 people with schizophrenia in a Japanese psychiatric hospital showed improved social

functioning, reduced time in hospital and reduced risk of hospitalization.[18] A Brazilian RCT investigating group and individual occupational therapy as an adjunct to Clozapine for 26 people with treatment-resistant schizophrenia found the experimental group significantly improved compared to usual care. However, the outcome measures for performance of activity, psychotic symptoms, social interaction and personal care relied on participant observation which may have introduced bias into the study. A further weakness of this study is that it did not have an active control group.[19]

The effectiveness of occupational therapy as an established mental health intervention has not been conclusively or systematically evaluated using controlled studies in any country. The aim of this study was to investigate the feasibility of a RCT design to inform a future fully powered study within a European health and cultural context. A parallel qualitative study illuminated the findings.

Methods

Study Design

Our study was a pragmatic, prospective, randomised controlled trial of community based occupational therapy as an adjunct to usual care for people with psychotic conditions. The pragmatic trial investigated the effectiveness of the experimental intervention in normal practice settings. A heterogeneous sample in terms of diagnosis was chosen in order to replicate clinical practice and increase the external validity of the findings (20). Similarly, participants were identified according to the diagnosis on their medical records rather than through a structured clinical screening process.

Participants

From June to December 2004, following ethical approval from the local ethics committee, 44 people over the age of 16 years were recruited by their care coordinators from two NHS

community mental health teams in a northern UK city that served diverse communities in terms of deprivation and ethnicity. Participants gave written consent after having the study explained to them in detail by one of the researchers. People were included with psychosis for any duration, eligibility for an enhanced care programme[21] and scoring 2 or more on at least one of the Health of the Nation Outcome Scales for problems with activities of daily living, disability or occupation and activities. People with dual diagnosis or physical/sensory disabilities were included but people with organic brain disorders were excluded.

Randomisation

Those consenting were randomised to allow a 1 in 3 chance of allocation to treatment as usual (TAU) and a 2 in 3 chance of allocation to occupational therapy plus usual care. This 2:1 ratio was selected at the request of the host teams who were concerned about restricting access for their clients to an established therapy. Randomisation used stratification by gender and treatment team, and random permuted blocks of sizes 3 and 6. A remote trials unit operated the computerised randomisation process and concealed the sequence and allocation from the research team by telephoning the treatment teams directly. The two assessors from the research team were blind to the allocation. The participants, therapists and care coordinators were aware of the allocation and were repeatedly reminded to keep the assessors blind. If blinding failed, the assessment was handed over to the other assessor who remained blind to allocation.

Interventions

Occupational therapy

The intervention schedule that defined occupational therapy was developed using consensus research methods with experienced practitioners, following a previous review of the literature and expert consultation.[22;23] The schedule specified an individualised and

client centred approach and comprised 82 components within the 11 stages of the occupational therapy process. The schedule can be accessed at: http://www.shu.ac.uk/research/hsc/downloads/Final%20Int%20Sched%20sequenced%20black%20and%20white.doc. The functions of the therapist were specified[24] such as to 'select and adapt activities to meet the individual goals of the client', but not the forms of therapy such as number of sessions, type of activity or venue, or the mix of individual and group sessions. The majority of components were specific to occupational therapy but a minority of generic components was included as these were required by all members of the multi-disciplinary team (e.g. risk management). The intervention schedule is summarized below:

The occupational therapist, involving family, other informal carers or staff as required:

- Engages with the client, establishing the client's preferences on how to work together and the client's history, interests and concerns regarding occupation.
- Assesses the client's competency in performing the client's routines, roles and occupations in daily life, including self care, productivity and leisure.
- Identifies the client's strengths and the barriers that impact on occupational performance, including the client's social and physical environments.
- Collaboratively sets and prioritizes goals concerning occupation and plans an individually tailored programme of therapeutic activities. These are selected and adapted using detailed activity and environmental analysis, grading and sequencing.
- Engages the client in planned activities, teaching specific skills and encouraging the client to initiate actions, use support, participate in group work, work alongside the therapist, or develop routines and balance of activities as planned.

- Reviews with the client the meaning and impact of the client's chosen activities, encouraging the client to develop strategies that use occupations to improve wellbeing and alleviate psychotic symptoms.
- Collaboratively continues assessing, reviewing outcomes, updating goals and modifying actions in order that the client achieves her or his desired occupations.

The intervention was delivered by three senior occupational therapists for up to 12 months for each participant. Within this period the number of sessions was not specified as this was tailored to each individual. Training was not given as the intervention was established occupational therapy practice. Performance was monitored through structured clinical supervision and adherence to the intervention schedule was audited using the participants' therapy notes.

Treatment as usual

This was provided by non-occupational therapist multi-disciplinary members of community mental health teams that specialised in the continuing care of people with psychotic conditions. Clients received medication, reviews by their psychiatrist and the enhanced level of care management specified by the UK Care Programming Approach.[25] The care coordinators provided a range of interventions and support from within the team and through referrals to other services. Team members had received training in psychosocial interventions that included relapse prevention strategies and family interventions and some were trained in psychological therapies.[26] These were delivered according to the needs of individual clients and the time that staff could offer, allowing for the demands of their caseloads.

Assessment

The interventions were delivered between June 2004 and Dec 2005. Assessment was performed at baseline, 6, 9 and 12 months, and data was collected in face to face interviews. No post-intervention follow-up was carried out. The first assessment was carried out at 6 months as advised by clinicians who reported that with this population improvement is not expected for some months. A limited number of outcome measures were chosen in order to maintain engagement with people who have limited concentration and high levels of distress. The primary measure was the Social Functioning Scale (SFS) which was developed and validated for people with schizophrenia.[27] Seven subscales measure withdrawal, relationships, social activities, recreation, independence competence, independence performance and employment. Raw scores are transformed to give each subscale equal weighting. The overall mean score ranges from 52 to 139, and the average point for this client group is 100. The secondary outcomes were negative symptoms of schizophrenia, measured with the Scale for the Assessment of Negative Symptoms (SANS)[28], and engagement in employment related activity within the last 3 months. Adverse events were recorded including suicide and psychotic relapse that required hospitalisation.

Inter-rater reliability

This was conducted for the SFS. We recruited 10 volunteers who attended local mental health day centres who were not participants of the trial. Both assessors interviewed each person individually using the SFS questionnaire and recorded the interviews on video. The assessors then rated each other's videos, to generate 20 pairs of assessment data using the SFS transformed total mean scores. A Bland-Altman chart was used to measure agreement between two sets of continuous data[29].

Statistical methods

Data analyses were based on an intention to treat principle unless stated otherwise. Missing values for any individual questions within the outcome measures were imputed using interpolation, when values were available either side of a missing time point the mean of the two values were imputed, otherwise the last observed value was carried forward. Baseline characteristics were summarised as number of subjects (%) for categorical data and mean (standard deviation) for continuous data. The outcome data was similarly summarised for the base line, six, nine and twelve months time points. T tests were carried out to compare scores over time and between groups and changes in clinical improvement were investigated using Fisher's exact test. Additional analyses included cross tabulation to investigate clinical significance and adjusting for base line differences using analysis of covariance (ANCOVA).

Results

Flow of participants through the trial

Six of the 50 people referred to the trail declined to take part. One person was about to move out of the area and the others did not disclose their reasons. Forty two out of 44 participants completed the trial. One person in each group received the intervention intended for the other group, through team members making referrals to other services. By the end of the trial the allocation for five people had become known to both assessors. See Fig 1.

Inter-rater reliability of the Social Functioning Scale

Overall mean scores showed a mean of 98.76 (range: 88.32 to 119.57) and standard deviation of 8.07. The results from measuring agreement between two sets of continuous data showed a mean difference and bias of -0.029, with a standard deviation of 0.761. The

limits of agreement were therefore -1.54 to 1.49. Relative to the range this is small and considered acceptable.

Base line characteristics

The age range was 18 – 60 years for the OT group and 21 – 56 years for the TAU group. The duration of psychotic condition ranged from 1 – 29 years for the OT group and 4 – 36 years for the TAU group. There were noticeable differences between groups in diagnosis and marital status due to chance in this small study, but these were not statistically significant. The OT group had a higher proportion of people diagnosed with 'other psychotic disorders' that included people who have not yet been given a definitive diagnosis, and a higher proportion of people who were married or living with a partner. The TAU group had a higher proportion of people with bipolar disorder. See Table 1.

Length of occupational therapy intervention

Of the 30 people in the OT group 83% received at least 11months of the 12months intervention. Eighteen received 12 months and 7 received 11 months. One participant decided to terminate therapy at 10 months, one went on a long holiday at nine months, two participants were discharged having achieved their goals at 8 months and 4 months. One person moved out of the area after one month. One person received no occupational therapy as shown in figure 1.

Outcomes

The mean scores for social functioning and negative symptoms, at each time point are shown for each group in Table 2.

Social functioning

Compared to base line, the OT group showed significant change at 12 months in the SFS overall mean scores (Mean difference = 2.33, CI: 0.39 to 4.27, t = 1.525, P= 0.020).

Compared to base line, the TAU group approached significant change at 6 months (Mean difference = 3.68, CI: -0.02 to 7.38, t = 2.19, P = 0.051); and achieved significant change at 9 months (Mean difference = 5.04, CI: 1.37 to 8.72, t = 3.00, P = 0.012); and at 12 months (Mean difference = 6.17, CI: 1.04 to 11.29, t = 2.65, P = 0.023). There was no significant difference between the two groups' change scores when compared at 6, 9 or 12 months.

Negative symptoms

The OT group showed significant improvement over time in the total SANS scores at 6, 9 and 12 months. The results were: at 6 months compared with base line: Mean difference = -9.615, CI: -16.04 to -3.19, t = -3.08, P = 0.005; at 9 months compared with base line: Mean difference = -11.885, CI = -18.31 to -5.46, t = -3.81, P = 0.001; and at 12 months compared with base line: Mean difference = -16.25, CI: -22.94 to -9.56, t = -4.99, P <0.001. The TAU group showed significant improvement in the total SANS scores at 6 and 12 months only. The results were: at 6 months compared with base line: Mean difference = -11.18, CI: -22.27 to -0.09, t =-2.25, P = 0.048; and at 12 months compared with base line: Mean difference = -17.36, CI: -29.78 to -4.94, t = -3.12, P = 0.011. There was no significant difference between groups on their change scores over time at 6, 9 or 12 months.

Outcomes adjusted for base line differences

As at baseline there were noticeable differences between the two groups on diagnostic categories, marital status, the SFS scores and SANS scores, the groups were compared using ANCOVA with change in SFS or SANS score over time used as the dependent variable. Table 3 shows that there was no significant difference between the groups even when adjusted on either SFS or SANS outcomes.

Clinically significant change

The OT group's social functioning subscales showed clinically significant improvement for certain subscales: relationships, independence performance and independence competence and the clinical improvement for recreation approached statistical significance (Table 4). Clinically significant change was defined as attaining a score of 116 or more, indicating that the person was no longer a cause for concern and did not require interventions[13]. The TAU group's subscales showed that clinical change was not statistically significant. Table 4 shows that very few people attained clinically significant improvement on their overall mean score. There were no statistically significant differences between the two groups at any time point.

A cross tabulation of the OT group's SANS scores showed clinical improvement from base line to 12 months that approached statistical significance (Table 3). The cross tabulation of the TAU group's SANS scores showed no clinically significant change using Fisher's Exact Test (P = 0.545). Clinically significant change was defined as attaining less than 3 in any subscale's global score as the SANS scales state that scores of 3 or more indicate a clinical problem.

There were no adverse events reported.

Qualitative findings

The parallel qualitative study which included 9 of the 12 people in the TAU group, showed that 4 of these participants received components of the occupational therapy intervention as described in the intervention schedule. This included tailoring support to the individual priorities and preferences of the client when choosing activities. These interventions were delivered by social workers, nurses or support workers. The qualitative study will be reported fully elsewhere.

Employment

In the OT group (n = 30), 3 participants were employed at baseline assessment, and a further 2 became employed during the intervention period. The control group (n = 12) had no-one employed at baseline and the person who inadvertently received occupational therapy became employed. The numbers were too small to compare groups.

Discussion

Statement of principle findings

Both groups improved significantly over time for social functioning and negative symptoms but there were no differences between the two groups on overall scores. The occupational therapy group showed clinically significant improvement in SFS subscales particularly for relationships, independence and recreation, and the clinically significant improvement in negative symptoms approached statistical significance. The TAU group did not show clinically significant changes. The small number of people engaging in employment related activity was disappointing.

Strengths and weaknesses of the study

The percentage of eligible participants who consented and completed the trial was extremely high (84%). We believe this to be a direct result of the significant involvement of service users in the design and the implementation of the study.[30] The study also recruited a high percentage of participants from minority ethnic groups (23%) compared to the local population of 10.9%.[31] This reflects the demography of this client group.

It was feasible to deliver occupational therapy that adhered to the intervention schedule but not feasible in the host setting to stop this intervention at 12 months as was intended in the protocol. This was due to concerns about continuity of care for vulnerable clients and

procedures are needed to manage this. One area for improvement in the design of this study was the use of care co-coordinators to identify eligible patients rather than sampling the whole case list. Some practitioners did not refer any of their patients. It may have been that only the most confident practitioners were prepared to engage in a study that was investigating their performance. This could have led to biased results and contributed to the positive results shown by the control group. Another improvement would have been to include an individualised outcome measure to complement the standardised measures, as discussed later.

The present study's findings re-iterate the reports of the few other relevant studies, that there is only suggestive evidence that mental health occupational therapy is effective for people with psychotic conditions. Three single cohort studies suggested that occupational therapy may be beneficial.[16] [17] [18] [19]

A drawback of the present study may have been that it did not target people's cognitive function, unlike an Israeli study of 58 people with schizophrenia that compared 12 months dynamic cognitive intervention applied to daily living situations and group therapy, to traditional occupational therapy, all delivered by occupational therapists.[32] The dynamic cognitive group showed improved scores for memory and thought processes, a higher percentage obtained work in the open market, but there were no difference for instrumental activities of daily living. The study was limited to a particular local population with unspecified ethnicity, so generalisability is restricted. In a UK RCT of cognitive rehabilitation compared to occupational therapy, both groups improved over time, but there were no between group differences post intervention, except for improved self-esteem in the cognitive rehabilitation group.[33]

Similarly, between group differences were not shown post intervention in an American RCT of skills training compared to occupational therapy except in measures of self-esteem.[34] Interestingly this study found that skills training showed significantly greater improvement on a measure of independent living skills at 2 year follow-up, after the community case managers had been instructed to encourage their clients to generalise the skills learned in the training sessions to every day situations. This suggests that rehabilitation interventions should be researched as an element of inter-professional practice with the contributions of all team members included in the research design.

Implications of the study

It could be argued that the study participants reached a limit in their potential to improve due to their long term disabling conditions. However, we suspect that limited improvement in the SFS overall score was due to a lack of sensitivity in the scores due to ceiling effects.[35] The OT and TAU groups reached 104 and 105 respectively post treatment. Similar studies reported scores of 108 following an integrated care programme,[36] 105 following occupational therapy and care management[16] and 104 following life skills training.[17] All these are below the clinically significant score of 116 at which no further intervention is required. Alternative instruments to measure function are recommended.

It was promising that occupational therapy was associated with some positive results concerning clinically significant improvement, beyond the average scores for this client group. Improvement in the social functioning subscales may have been due to the individually tailored occupational therapy programmes that were designed around each person's unique aspirations for their daily lives. Such individualised programmes may contribute towards meaningful recovery but are not designed to improve a person’s overall functioning.

Unanswered questions and future research

A study objective was to estimate parameters for future trials and these results will be used to inform the power calculation for a larger study. However, standardised measures may not be sensitive to improvement in a discreet area of living that has been targeted by an individually tailored programme. For instance, one of the study participants focused only on passing a GCSE at college and his achievement was not reflected in his outcome scores. It may be advisable in similar studies to add an individualised measure such as Goal Attainment Scaling, the Canadian Occupational Performance Measure or Seiqol.[37;38]

The major challenge to the feasibility of the study was the contamination between the two groups, with evidence from the parallel qualitative study that some treatment as usual participants received occupational therapy. Contamination could have been due to inter-disciplinary working over a long period of time, with occupational therapy being an established rather than a new intervention. Team members usually discussed cases together and practiced joint working with the occupational therapists. They shared strategies and information on accessing community resources and facilitating clients to engage in activities of their choice. This could contribute to occupational therapy not being separate or additional to the routine practice of social workers and nurses. Lack of difference between the two groups' outcomes may also have been due to:

a) chance: the study was not powered to detect significant differences between groups
b) variation in the therapists' and care coordinators' qualities rather than particular psychosocial interventions[39]
c) the positive impact of medication and psychosocial interventions on both groups
d) a positive Hawthorn effect on staff when providing the control intervention, in response to their practice being scrutinised

e) the attention that was paid to the control group during repeat interviews and from the efforts of the research team to validate and retain their participation, including newsletters, greetings cards, payments of £10 shopping vouchers for each interview.

This study demonstrates the preliminary steps for the design and evaluation of complex interventions leading to recommendations for the development of improved trials in the future.[40]

To conclude, this pilot study suggested that individualised occupational therapy may contribute to recovery but more focus is recommended on people's cognitive abilities and employment. Although the results of this small study were not intended to be generalisable, the findings merit further studies. It is worth carrying out a future fully powered study of mental health occupational therapy, not as an isolated intervention, but within inter-professional practice. Suitable designs include a multi-centre cluster randomised trial with the team as the unit for randomisation or observational studies to provide supportive data.[41] To do this, outcome measures are required that are sensitive to the changes associated with individualised programmes of therapy and therapists' qualities need to be factored in.

Clinical Message

- Limited evidence found individualised occupational therapy was associated with clinical improvement in social functioning and negative symptoms for people with psychotic conditions.

- Future research designs should investigate occupational therapy within inter-professional practice in mental health settings.

- Individualised outcome measures are required to investigate client-centred programmes of therapy.

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Competing interests

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Table 1. Baseline characteristics of people with psychotic conditions who were randomised to occupational therapy or treatment as usual

Characteristic	OT n = 30	TAU n = 14	Total n = 44
Mean age (SD)	38.63 (10.9)	39 (8.6)	39
Duration of psychotic condition in years (SD)	12.27 (7.82)	13.79 (9.15)	13
Gender (%)			
Female	10 (33.33)	5 (35.71)	15
Male	20 (66.67)	9 (64.29)	29
Ethnicity (%)			
White British	23 (76.67)	11 (78.57)	34
Other	7 (23.33)	3 (21.43)	10
Diagnosis (%)			
Schizophrenia	20 (66.67)	8 (57.14)	28
Bipolar*	3 (10.00)	5 (35.71)	8
Other psychotic disorder*	7(23.33)	1 (7.14)	8
Employed (%)	2 (6.67)	1 (7.14)	3
Education level (%)			
Not completed compulsory	1 (3.33)	0 (0.00)	1
School up to age 16	6 (20.00)	6 (42.86)	12
Further education 16 +	21 (70.00)	7 (50.00)	28
Degree level	2 (6.67)	1 (7.14)	3
Accommodation (%)			
Own/rented	24 (80.00)	12 (85.71)	36
Own/rented with support	1 (3.33)	1 (7.14)	2
Residential/nursing home	3 (10.00)	1 (7.14)	4
Homeless	2 (6.67)	0(0.00)	2
Living alone (%)			
Lives alone	16 (53.33)	8 (57.14)	24
Lives with other people	14 (46.67)	6 (42.86)	20
Marital status (%)			
Married/living with partner*	7 (23.33)	1 (7.14)	8
Separated/divorced*	3 (10.00)	5 (35.71)	8
Single*	19 (63.33)	8 (57.14)	27
Other	1 (3.33)	0 (0.00)	1

* Noticeable differences between groups (differences are not statistically significant)

OT: occupational therapy, TAU: treatment as usual, SD: standard deviation

Table 2: Outcome scores over time for the occupational therapy and treatment as usual groups

	Baseline		6 months		9 months		12 months		Change score, baseline to 12 months	
	Occupational therapy	Treatment As Usual	Occupational therapy	Treatment As Usual	Occupational therapy	Treatment As Usual	Occupational therapy	Treatment As Usual	Occupational therapy	Treatment As Usual
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
SFS	N = 30	N = 14	N = 29	N = 12	N = 30	N = 12	N = 28	N = 12	N = 30	N = 12
SFS overall mean	101.7 (7.3)	100.3 (8.6)	102.3 (7.9)	102.9 (7.5)	104 (8.5)	105.3 (9.4)	103.4 (9.7)	104.2 (7.7)	2.3 (5.2)	6.2 (8.1)
Social Withdrawal	99 (9.8)	97.3 (9.5)	99.9 (12.3)	99.6 (8.70	103 (10.1)	101.8 (10.3)	102.9 (11.8)	100.4 (11.1)	4 (9.2)	5 (11.7)
Relationships	108.9 (19.1)	102.7 (13.1)	113.7(20.7)	108.4 (8.3)	111.8 (18.9)	116.1 (17.6)	114.8 (19.1)	111.4 (13.7)	2.8 (14.5)	14.9 (20.3)
Social Activities	108.4 (10.9)	105.5 (6.5)	104.3 (9.5)	105.9 (12.8)	107 (10.4)	110.9 (9)	106.2 (10.8)	108.5 (8)	-1.4 (10.3)	6.4 (8)
Recreational Activities	98.2 (11.9)	99 (17)	96.8 (16.4)	98 (12.3)	102.3 (16.6)	102.4 (15.7)	99.7 (16.6)	100.9 (16.3)	4.1 (12.7)	4.1 (11.9)
Independence Competence	102.5 (12.2)	101.6 (18.8)	106 (15.3)	108.9 (15.2)	105.1 (13.1)	108.1 (17.3)	104.8 (13.9)	109.5 (12.2)	2.6 (8.5)	8.5 (14.4)
Independence Performance	101 (9.8)	97.9 (14.5)	101.5 (11.8)	104 (16.8)	102.9 (10.4)	102.1 (15.1)	101.7 (12.6)	103.7 (15)	1.9 (9)	4.7.1 (13.8)
Employment	93.9 (7.6)	98.3 (7.70	94.2 (9.2)	95.3 (7.4)	96.2 (9.7)	96 (10.8)	93.8 (9.2)	95.1 (11.5)	2.3 (7.9)	-0.4 (10.1)
SANS	N=29	N=12	N=27	N=12	N=29	N=12	N=27	N=11	N=28	N=11
Total	39.5 (23.1)	30.1 (21.6)	27.3 (16.5)	20.3 (10.1)	22.9 (19.2)	14.2 (11.9)	28.4 (21.1)	18.2 (12.2)	-16.2 (17.2)	-17.4 (18.5)
Blunting	10.2 (8.8)	5.8 (8.7)	6.9 (6.9)	2.4 (3.5)	5.8 (7.1)	0.8 (2.3)	6.9 (7.5)	2.1 (3.0)	-4.2 (6.3)	-5.4 (7.6)
Alogia	5.5 (5.3)	2.7 (5.4)	2.7 (2.5)	1.1 (2.6)	2.7 (3.3)	1.3 (2.5)	3.5 (4.4)	1.6 (3.1)	-2.8 (4.7)	-1.4 (4.3)
Apathy	9.7(5.1)	8.1 (6.1)	7.6 (4.3)	7.8 (4.2)	5.7 (4.9)	5.7 (3.7)	7.6 (4.7)	7.1 (4.6)	-3.9 (4.1)	-3.2 (5.5)
Asociality	9.8 (5.4)	9.2 (4.9)	6.4 (5.2)	6.3 (3.4)	5.8 (5.4)	4.0 (3.7)	6.0 (5.4)	4.6 (3.2)	-3.7 (4.8)	-5.4 (7.5)

Attention	4.3 (3.7)	4.4 (3.5)	3.7 (3.8)	2.8 (2.6)	3.0 (3.5)	2.5 (4.5)	4.3 (4.0)	2.9 (4.6)	-1.7 (3)	-1.9 (2.9)

For the SFS higher scores indicate improvement. For SANS lower scores indicate improvement.

SD: standard deviation, SFS: Social Functioning Scale, SANS: Scale for the Assessment of Negative Symptoms

Table 3: Difference in outcome scores between intervention groups: Unadjusted and adjusted for key base line factors using ANCOVA

Variable	N	Coefficient of the regression (difference)[a]	95% CI	P value
SFS overall mean				
Unadjusted difference	42	-0.987	-6.551 to 4.576	0.722
Difference adjusted for baseline SFS overall mean score	42	-3.124	-6.478 to 0.230	0.067
Difference adjusted for diagnostic groups[b]	42	-2.879	-6.462 to 0.703	0.112
Difference adjusted for marital status[b]	42	-2.804	-6.169 to 0.561	0.100
SANS total score				
Unadjusted difference	39	9.410	-2.54 to 21.363	0.119
Difference adjusted for baseline SANS Total score	39	5.799	-2.972 to 14.569	0.188
Difference adjusted for diagnostic groups[b]	39	6.117	-3.365 to 15.598	0.199
Difference adjusted for marital status[b]	39	6.520	-2.411 to 15.452	0.147

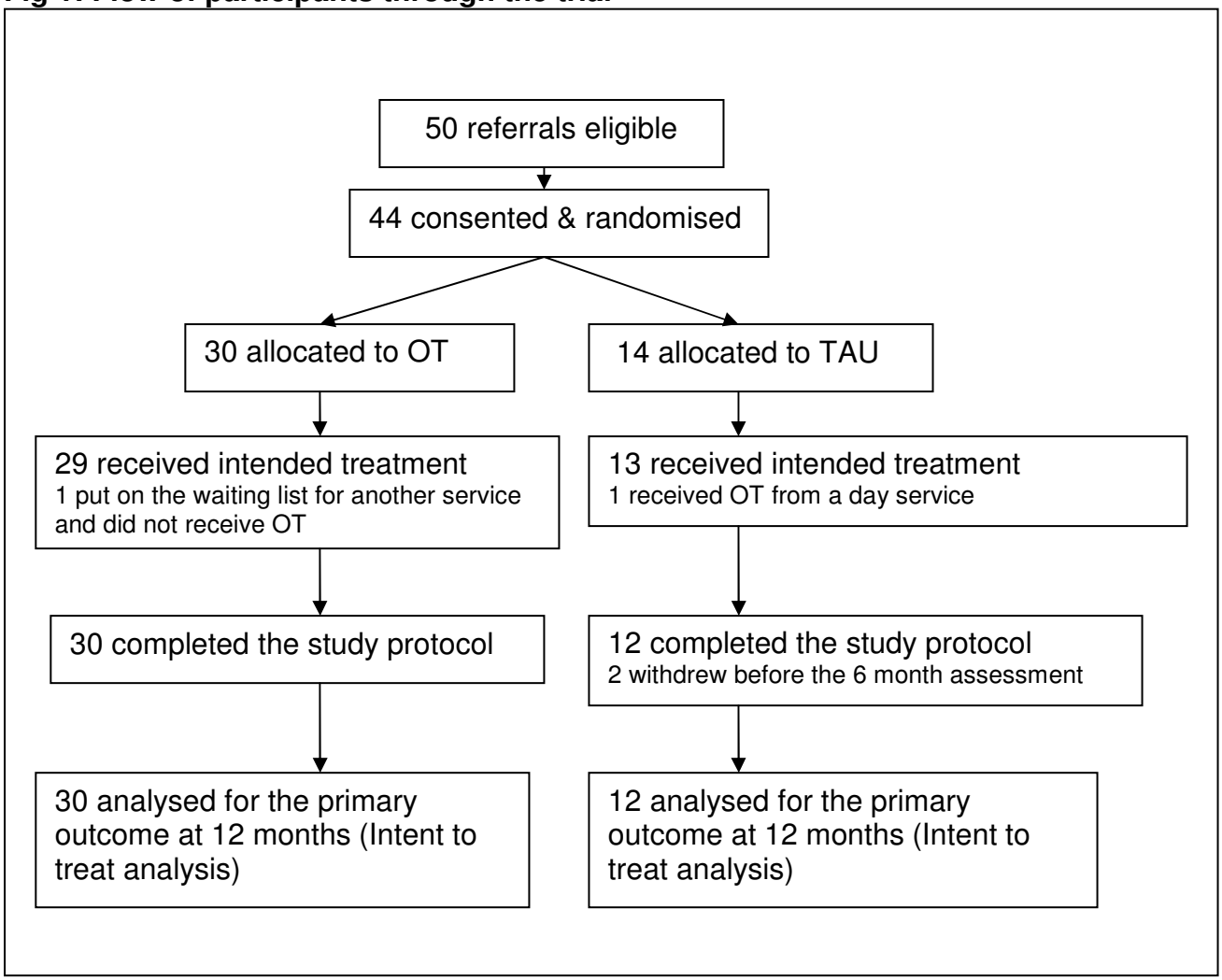
a For SFS higher scores indicate higher function and for SANS higher scores indicate more severe problems
b Also adjusted for the baseline outcome score
SFS: Social Functioning Scale, SANS: Scale for the Assessment of Negative Symptoms

Table 4: Clinically significant change in the two intervention groups over 12 months for social functioning and negative symptoms

	Occupational therapy			Treatment as usual		
SFS	**Number of participants scoring ≥ 116 (%)**		**P value[1]**	**Number of participants scoring ≥ 116 (%)**		**P value[1]**
	Base line	12 months		Base line	12 months	
Overall mean	2 (6.7)	2 (6.7)	No change	0 (0)	1 (8.3)	N/A[2]
Social withdrawal	3 (10.0)	6 (20.0)	0.501	1 (8.3)	2 (16.7)	1.000
Relationships	8 (26.7)	11 (36.7)	0.028	1 (8.3)	5 (41.7)	1.000
Social activities	5 (16.7)	5 (16.7)	No change	2 (16.7)	2 (16.7)	No change
Recreation	2 (6.7)	8 (26.7)	0.064	2 (16.7)	3 (25)	0.455
Independence performance	2 (6.7)	3 (10.0)	0.007	2 (16.7)	1 (8.3)	0.167
Independence Competence	5 (16.7)	7 (23.3)	0.006	3 (25)	6 (50)	1.000
Employment	1 (3.3)	3(10.0)	0.100	1 (8.3)	1 (8.3)	No change
SANS	**Number of participants with any global score < 3 (%)**		**P value[1]**	**Number of participants with any global score < 3 (%)**		**P value[1]**
	Base line	12 months		Base line	12 months	
	10 (35.7%)	15 (53.6%)	0.055	3 (27.3%)	6 (54.5%)	0.545

1:Fisher's Exact; 2: No statistics computed because of a constant variable in the 2 way cross tabulation
SFS: Social Functioning Scale; SANS: Scale for the Assessment of Negative Symptoms

Fig 1: Flow of participants through the trial



OT: occupational therapy, TAU: treatment as usual