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Research Paper

Twelve months effect of self-referral to inpatient treatment on patient activation, recovery, symptoms and functioning: A randomized controlled study



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ABSTRACT

Objective: To investigate the effect of having a contract for self-referral to inpatient treatment (SRIT) in patients with severe mental disorders.

Methods: A randomized controlled trial with 53 adult patients; 26 participants received a SRIT contract, which they could use to refer themselves into a Community Mental Health Centre up to five days for each referral without contacting a doctor in advance. Outcomes were assessed after 12 months with the self-report questionnaires Patient Activation Measure (PAM-13), Recovery Assessment Scale (RAS), and the Behavior and Symptom Identification Scale (BASIS-32) and analyzed using linear mixed and regression models.

Results: There was no significant effect on PAM-13 (estimated mean difference (emd) -0.41, 95% CI (CI):-7.49–6.67), nor on the RAS (emd 0.02, CI:-0.27–0.31) or BASIS-32 (0.09, CI:-0.28–0.45). An exploratory post hoc analysis showed effect of SRIT in those with low PAM below \leq 47 (p=0.049).

Conclusion: There were no group differences after 12 months, but both groups maintained their baseline levels.

Practice implications: SRIT contracts can be recommended as it supports the rights to self-determination, promote user participation in decision-making in own treatment without any indication of adverse effects.

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1. Introduction

Shared decision making and the right to self-determination are important ethical aspects in mental health services [1,2].

Such aspects are not well implemented in mental health services at present [3]. Thus, there is a need for service models offering patients to be empowered as decision-makers [4,5], get involved as active partners [6] and participate in treatment decisions [7].

Patient activation is defined as knowledge, skills and confidence in managing one's own health [8]. Being active and engaged has been associated with improved health outcomes and positive experience with care, and better coping skills and recovery [9]. Conversely, patients with low levels of activation may be too

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overwhelmed to manage their own health, and have low confidence and insufficient problem-solving skills [10]. Regaining authority through being self-empowered with support is required for re-establishing and stabilizing the hope of recovery [11]. Participation in decisions empowers individuals and promotes their personal recovery [12]. Personal recovery is defined as a process of "changing one's attitudes, values, feelings, goals, skills, and/or roles" for "living a satisfying, hopeful and contributing life", even while living with a disease [13]. Such recovery requires that persons with severe mental disorders establish a meaningful life through taking more control over their lives in spite of their disorders [14]. In addition to improved personal confidence and willingness to ask for help, there is focus on goal and success orientation, reliance on others and avoiding domination by symptoms [15].

People with severe mental disorders occasionally need treatment from inpatient services in phases with increased symptoms and crises [16]. A flexible, safe and predictable support from the services will facilitate the patients' coping in those phases [17]. Self-referral to inpatient treatment (SRIT) might be one way to obtain that [18]. SRIT has recently been implemented in several Community Mental health Centers (CMHC) in Norway [19–26]. This intervention is based on legislation regarding patients' rights [27], personalized care planning [28] and shared decision making [29]. SRIT seems to be a flexible model adapted to patients' needs [23]. A recent systematic review of published reports on SRIT found only qualitative and observational studies [18]. However, two recent randomized controlled trials, evaluated the effect of SRIT. Both studies and the present study are parts of a larger study investigating the effect of introducing SRIT. One study found no effect of SRIT in re-admissions, inpatients days, and coercion after 12 months [22]. The other study found no effects on patient activation and recovery after 4 months [21]. It would therefore be important to investigate the effect of SRIT after 12 months regarding activation, recovery, mental health symptoms and functioning. Such information has not been reported.

Objectives: The main aim was to assess the effect of a SRIT contract on the primary outcome patient activation (PAM-13). The secondary outcomes were recovery (RAS) and behavior and symptoms identification (BASIS-32) after 12 months compared to those who received treatment as usual (TAU).

2. Methods

2.1. Trial design

An open parallel-group randomized, and controlled trial (RCT) was conducted at a CMHC in central Norway. The inclusion period was between May 2010 and December 2012.

The project had one user representative in the management group and two user researchers in the research group. The trial was registered at clinicaltrials.gov (NCT01133587).

2.2. Settings

The catchment area for the CMHC in Central Norway is 94,000 inhabitants.

2.3. Participants

The main inclusion criteria were adults clinically diagnosed with schizophrenia or bipolar disorder. Some had several diagnoses and comorbid drug addiction. The drug use should be relatively under control. They needed to have had previous contact with the CMHC rehabilitation unit, and to have had continued long-term primary and specialist healthcare outpatients consultations. The exclusion criteria were severe substance abuse problems or self-destructive behavior, inability to consent, or being unable to use SRIT as intended. An interdisciplinary team at the CMHC decided who was eligible for the study.

The recruitment took place by informing patients and staff both orally and in writing. The participants either volunteered themselves or were recommended by their therapists. All participants had to be approved by a specialist in psychiatry. They could either be inpatient or outpatient before they were included into the study, but they needed to be discharged the same day or within a few days. Thirty-three (62.3%) participants (18 in SRIT, 15 in TAU) were included and randomized while they were inpatients, and they stayed for an average of 13.6 days.

2.4. Intervention

The purpose of a SRIT contract was to increase user participation and to offer patients with worsening symptoms easy access to inpatient treatment without the need to contact the doctor. All participants in this study received exemplified information about how to use SRIT prior to inclusion (e.g. structure during the day, or experienced warning signs and worsening symptoms of their mental disorder). All were encouraged to establish an individual plan, as all patients with severe mental disorders have a right to have [30]. Participants were informed that if they were randomized to TAU, a SRIT contract would be offered after one year if they still fulfilled the inclusion criteria. The guidance in how to use the contract was repeated to each SRIT participant after randomization. The participants were encouraged to discuss their warning signs and what they could do to reduce them with their therapist.

SRIT participants could self-refer to the rehabilitation section between Mondays and Friday between 8:00 a.m. and 8:00 p.m. for up to five days. If they wanted to stay over the weekend, they had to contact the unit before 3:30 p.m. on Friday. A minimum of 14 days between each stay was enforced, which was done to avoid capacity problems and based on procedures from the first study in Norway [19]. Participants were invited to follow the units' usual rules and structure. All SRIT patients had a consultation with a specialist nurse in psychiatry after referral who documented in the health record on the basis of the consultation. Consultations with a doctor or psychologist were not planned, but could be arranged. Their medication plans should normally not be changed during the stay, but changes were possible under doctors' instruction. All patients could be admitted to the CMHC or hospitals by a doctor following normal procedures. Participants randomized to TAU followed usual procedures if they needed hospitalization.

2.5. Outcomes

The outcomes were assessed at baseline and after 12 months. A few participants completed the surveys at home. The rest completed the self-report questionnaires at the CMHC by themselves. A few needed assistance to complete the scales.

2.5.1. Primary outcome

The primary outcome Patient Activation Measure (PAM-13) is the most frequently used measure of activation in health care [7]. It measures both patient's beliefs about their ability to self-manage and their confidence to take action [7]. The translated [31] and validated Norwegian PAM-13 was used [31,32]. PAM-13 is a 13item, self-report questionnaire measuring knowledge, skills and confidence in managing one's health, which is scored on a fourpoint Likert scale from 1 = strongly disagree to 4 = strongly agree, additionally 0 = not applicable [8,33]. The PAM-13 raw scores (sum score) were converted into a theoretical range of 0–100 [33] and can be divided into four levels where 1 = may not yet believe activation is important (\leq 47.0), 2=a lack of confidence and knowledge in taking action (47.1–55.1), 3=beginning to take action (55.2–67.0), and 4=taking action (\geq 67.1) [34]. These levels may be used as cut-offs for stratifying data [34].

2.5.2. Secondary outcomes

Recovery (RAS) is developed to measure personal perspective on recovery among patients with severe mental disorders [15] and is a commonly used measure [15,35]. RAS is validated [15,35] and comprises 24 items that measure recovery from severe mental disorders on a five-point Likert scale, going from 1, which is completely disagree, to 5, which is completely agree [15]. The scale assesses five validated factors: 1, personal confidence and hope (nine items; range 9–45); 2, willingness to ask for help (three items; range 3–15); 3, goal and success orientation (five items; range 5–25); 4, reliance on others (four items; range 4–20); and 5, no domination by symptoms (three items; range 3–15) [15,36]. The scale was translated into Norwegian for this study using forward and backward translation with two people conducting each translation.

Behavior and Symptoms Identification Scale (BASIS-32) is developed to measure symptom and functioning difficulties that lead to a need for mental health services [37]. BASIS-32 is a commonly used measure in mental health [37]. Basis-32, includes 32 items on a five-point Likert scale, where 0 indicates no difficulties and 4 indicates severe difficulties [37]. The scale measures five factors: 1, relation to self and others (seven items); 2, depression/anxiety (six items); 3, everyday life and role functioning (nine items); 4, impulsive and addictive behavior (six items); and 5, psychosis (four items) [37]. Factors 1, 2, 4 and 5 are assessed using the total score, divided by the number of items answered (mean scores), while factor 3 uses the highest rating. BASIS-32 has been validated [38], translated and retranslated from English to Norwegian in accordance with current standards.

2.6. Sample size

The sample size calculation was based on a two sample *t*-test to find a difference in PAM-13 scores among groups of 10. With an equal standard deviation (SD) of 11, significance level of 0.05 and 80% power, 21 participants were required in each arm. To allow for drop-outs, the sample size was set to 60 participants. The SD of 11 was based on the results from the Norwegian validation of PAM-13 among patients with somatic disorders [31].

2.7. Randomization

A block randomization was completed using a web-based randomization system (WebCRF, version 1.3), which was developed and administered by Norwegian University of Science and Technology, Trondheim, Norway. The randomization was balanced 1:1, and stratified by whether or not patients were using a special outpatient follow-up service (Psychiatric Ambulatory Rehabilitation Team), which was assumed to provide extra support.

2.8. Blinding

No ordinary blinding was done, but the statistician who analyzed the data was blinded to group allocation.

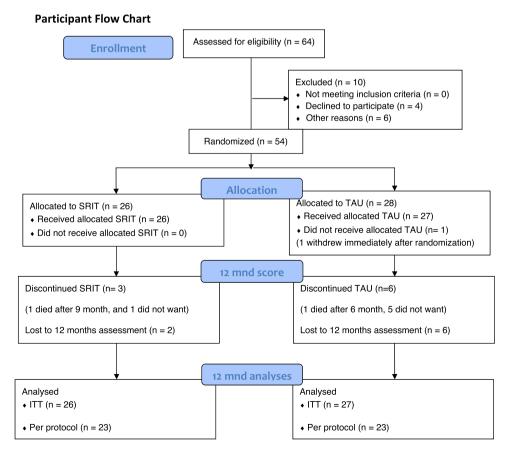


Fig. 1. Flow chart.

2.9. Ethics

The trial was approved by the Regional Committee for Medical and Health Research Ethics in East –Norway (no 2009/1704). All participants signed consent forms prior to the study. No compensation for participation was given.

2.10. Statistics

The characteristics of the participants for both groups were analyzed using two-tailed Mann Whitney *U* tests, independent sample *t*-tests, and Chi square tests of distributions.

The effects of the intervention were analyzed according to the intention to treat principle (ITT) [39] and per protocol, using a linear mixed model. This models uses all available data in the presence of dropouts, and there is no need for multiple imputations [40]. The per-protocol analysis only included participants who completed the protocol for their allocated treatment and who had the opportunity to use the contract. Those who could not use the contract (e.g. moved, died, had long-term hospitalization) were excluded.

Patient identification was specified as a random effect, accounting for the within-subject correlation. The effect of intervention and time was specified as fixed with the following three levels: baseline, TAU after 12 months and SRIT after 12

months. A 10-year age difference (p = 0.002) between the groups at baseline was identified and age was found to be an important predictor for PAM and RAS. Thus, an additional linear mixed model analysis with age added as covariate was performed.

Supplementary post-hoc linear regression analyses were performed to assess the effect of the intervention for patients with PAM-13 \leq 47, using the cut off points for those with the lowest activation level [34]. The dependent variable was the change in PAM-13 from baseline to 12 months. The independent variables were dichotomized baseline PAM-13 \leq 47 and >47 and SRIT vs. TAU. Corresponding analyses were performed for RAS and BASIS-32 using their 50th percentiles for dichotomization.

The confidence interval (CI) was set to 95% for all statistics and the p- value was set to \leq 0.05. No interim analysis or stopping guidelines were used. Missing data was managed according to the guidelines of the questionnaires used. The statistical analyses were carried out using IBM corp. SPSS, version 22.0 [41] and R version 2.13.1 [42].

3. Results

3.1. Participants

The flow of the participants is shown in Fig. 1. Of the 64 eligible participants, a group of 10 had not completed their inpatient

Table 1

Service user characteristics at baseline for SRIT and TAU, and observed value of PAM-13, BASIS-32 and RAS at baseline and 12 months.

| | SRIT | TAU | р |
|---|---------------|---------------|-------------------|
| | n=26 | n=27 | 1 |
| Age Mean (SD) | 45.7 (12.6) | 35.2 (11.7) | 0.002 |
| Gender n (%) | | | 0.50 ^b |
| -Woman | 12 (46.1) | 10 (37.0) | |
| -Men | 14 (53.9) | 17 (63.0) | |
| Diagnosis (ICD 10) | | | |
| Schizophrenia and bipolar disorders | | | 0.30 ^b |
| –Schizophrenia disorders | 18 (69.2) | 22 (81.5) | |
| -Bipolar disorders | 8 (30.8) | 5 (18.5) | |
| -Comorbid diagnosis | 10 (38.4) | 7 (26.0) | 0.24 ^b |
| -Substance disorder | 8 (30.8) | 5 (18.5) | 0.31 ^b |
| -Living situation | | | |
| -Living in relation with other | 4 (15.4) | 3 (11.1) | |
| -Living alone | 22 (84.6) | 24 (88.9) | |
| Life income | | | |
| -Work | 1 (3.8) | 1 (3.7) | |
| -Sickness benefits/courses /disability/retirement/ | 22 (84.6) | 22 (81.5) | 0.94 ^c |
| student | 3 (11.5) | 4 (14.8) | |
| Psychiatric Ambulatory Rehabilitation Team (PART) n (%) | 8 (30.8) | 10 (37) | 0.63 ^c |
| Observed value: | | | |
| Baseline outcome (mean, SD) | | | |
| -PAM-13 | 64.12 (16.09) | 63.89 (15.29) | 0.96 ^a |
| -BASIS-32 | 1.13 (0.74) | 1.40 (0.74) | 0.20 ^a |
| -RAS | 3.79 (0.67) | 3.59 (0.79) | 0.32ª |
| 12 months outcome (mean, SD) | | | |
| -PAM-13 | 65.64 (16.78) | 65.07 (16.70) | 0.91 ^a |
| -BASIS-32 | 1.17 (0.87) | 1.21 (0.81) | 0.87 ^a |
| -RAS | 3.93 (0.68) | 3.81 (0.71) | 0.56 ^a |

SRIT = Self-referral to inpatient treatment.

TAU = Treatment as usual.

SRIT = Self-referral to inpatient treatment.

TAU = Treatment as usual.

PAM -13 = Patient activation Measure.

BASIS-32 = Behaviour and Symptom Identification Scale.

RAS = Recovery assessment Scale.

^a = Independent *t*-test (two-tailed).

^b = Chi squares $(2 \times 2, \text{ two-tailed})$.

^c = Mann-Whitney *U* test.

treatment, did not meet the inclusion criteria or did not want to participate, leaving 54 patients to be randomized into the study. One patient in the TAU group withdrew after randomization. The final sample contained 53 participants, with 26 patients in the SRIT group and 27 patients in the control group. Seven patients could not complete the intervention period and were excluded from the per-protocol analyses (two died, two moved, two withdrew, and one was long-term hospitalized).

3.2. Baseline data

The mean age of participants was 40.4 (range: 21–73, SD 13.1), with 22 females and 31 males (Table 1), where those in SRIT were on average 10 years older than those in TAU. There were no significant differences in gender distribution between the groups and nearly all patients lived alone and received disability benefits. Complementary analyses were also done for other baseline characteristics (diagnosis, living situation and life income), but with non-significant results, and are not shown.

3.3. Implementation of intervention

Twenty-three of the 26 SRIT participants (88%) completed the intervention and 20 of the SRIT participants (77%) used the SRIT contract actively. The median was 1.5 admissions and 5 inpatient days during the 12-month period. More information is given in the recent paper of Sigrunarson et al. [22].

3.4. Outcome

3.4.1. Intention to treat and per protocol analyses

The mean scores at 12 months for the main outcome PAM-13 were 65.51 in SRIT and 65.92 in TAU (Table 2), and they were not significantly different. The estimated difference in mean (est. diff) was -0.41, (95% CI = -7.49-6.67, p = 0.91). There were no significant differences on either of the secondary outcomes. The mean scores of RAS were 3.86 for SRIT and 3.84 for TAU (est. diff 0.02, 95% CI: -0.27-0.31, p = 0.90). The BASIS-32 scores were for SRIT 1.27 and for TAU 1.18 (est. diff 0.09, 95% CI: -0.28-0.45, p = 0.63) (Table 2). The per-protocol analyses also revealed non-significant differences (Table 3).

3.4.2. Age as covariate (model based mixed model adjusted for age) No significant differences between the SRIT and TAU groups were seen in PAM-13 (p = 0.58), RAS (p = 0.80) or BASIS-32 (p = 0.49) when the mixed model was adjusted to age 40.4 (mean age at baseline) and to age 41.4 at the end of the 12 months (Table 4). 3.4.3. Post hoc analysis of interaction between baseline PAM-13 and treatment group on change in PAM-13

There was an interaction effect between the dichotomized baseline PAM-13 and the treatment group (p = 0.046), six patients (three in each group). Among those with PAM \leq 47, the effect of SRIT compared to TAU was estimated at 19.53 (CI 0.03–39.04, p = 0.049). For those with PAM > 47, the effect of SRIT compared to TAU was estimated at -2.63 (CI 10.51–5.25, p = 0.51).

3.4.4. The interaction between baseline RAS and treatment group on change in RAS; and for baseline BASIS-32 and treatment group on change in BASIS-32

There was no significant interaction between the dichotomized baseline RAS (to lower or higher than the 50% percentile) and the treatment group on change in RAS. A corresponding analysis showed the same for BASIS-32.

3.4.5. Changes within groups

There was no significant difference within groups in PAM-13 (Table 2). The recovery factor, "willingness to ask for help" changed significantly from baseline to 12 months within the SRIT group, (est. diff 0.38, 95% CI: 0.01–0.76, p = 0.05) (Table 5). There were no significant within-group differences in the other factors of RAS and BASIS-32 (Table 5).

4. Discussion and conclusion

4.1. Discussion

Contrary to the expectations, there were no significant group differences for PAM-13, RAS and BASIS-32. However, an explorative post hoc analysis indicated that patients with low activation in SRIT had more improvement on PAM-13 compared with those in TAU. There was no evidence for any deterioration as a result of the intervention; The outcomes were stable during the 12 months.

Twenty of the 26 SRIT participants (77%) used the SRIT contract actively. There were no significant group differences between SRIT and TAU in total number of inpatient days [22]. Both groups decreased their total number of inpatient days about 40% [22]. This parallels previous studies which have reported decrease in total inpatient days for SRIT participants [19,25,26], but those reports [19,25,26] lacked a control-group. Since our control-group had the same reduction in inpatient days, we cannot ascribe the reduction to the SRIT intervention. These studies also reported increased number of admissions, which is in line with our SRIT participants [22].

There was no significant group difference in patient activation during 12 months SRIT intervention, accordingly SRIT did not

Table 2

Model based mixed model, ITT analyses from baseline to 12 months, within and between each group.

| Out come | Mean at baseline | | | Means at 12-months | | | Withi | Between groups, at 12 months | | | | | | |
|----------|------------------|---------|-------|--------------------|---------|-------|--------|------------------------------|------|------|-------|---------|------|------|
| | Mean | 95 % CI | | Mean | 95 % CI | | change | 95 % CI | | р | diff | 95 % CI | | р |
| PAM-13 | 64.0 | 59.67 | 68.34 | | | | | | | | -0.41 | -7.49 | 6.67 | 0.91 |
| -SRIT | | | | 65.51 | 59.89 | 71.13 | 1.50 | -3.55 | 6.56 | 0.56 | | | | |
| -TAU | | | | 65.92 | 60.01 | 71.83 | 1.91 | -3.46 | 7.29 | 0.49 | | | | |
| RAS | 3.69 | 3.50 | 3.88 | | | | | | | | 0.02 | -0.27 | 0.31 | 0.90 |
| -SRIT | | | | 3.86 | 3.62 | 4.10 | 0.17 | -0.04 | 0.38 | 0.11 | | | | |
| -TAU | | | | 3.84 | 3.59 | 4.10 | 0.15 | -0.07 | 0.37 | 0.18 | | | | |
| BASIS-32 | 1.27 | 1.05 | 1.48 | | | | | | | | 0.09 | -0.28 | 0.45 | 0.64 |
| -SRIT | | | | 1.27 | 0.99 | 1.55 | 0.00 | -0.26 | 0.26 | 0.99 | | | | |
| -TAU | | | | 1.18 | 0.88 | 1.48 | -0.09 | -0.36 | 0.19 | 0.53 | | | | |

PAM-13 = Patient Activation Measure (range from 0–100, an increase in scores indicates improvement). BASIS-32 = The Behaviour and Symptom Identification Scale (range 0– 128, a decrease in scores indicates improvement). RAS = Recovery Assessment Scale (range 24–120, an increase in scores indicates improvement).

Table 3

Model based mixed model, per protocol analyses from baseline to12 months, within and between each group.

| Out come | | Mean at baseline | | | Means at 12-months | | | Within gr from base | oups, eline to 12 r | Between groups, at 12 months | | | | | |
|-------------|------|---------------------|-----|-------|-----------------------|--------|-------|------------------------|------------------------|---------------------------------|------|------|--------|------|------|
| | | Mean | 95% | % CI | Mean | 95% CI | | change | 95% CI | | р | diff | 95% CI | | р |
| PAM-13 | 62.8 | 58.3 | 9 | 67.15 | | | | | | | | 1.44 | -5.68 | 8.57 | 0.69 |
| -SRIT | | | | | 65.48 | 59.92 | 71.05 | 2.71 | -2.43 | 7.85 | 0.30 | | | | |
| -TAU | | | | | 64.04 | 58.16 | 69.91 | 1.27 | -4.21 | 6.74 | 0.65 | | | | |
| RAS | 3.65 | 3.44 | | 3.86 | | | | | | | | 0.03 | -0.27 | 0.33 | 0.85 |
| -SRIT | | | | | 3.82 | 3.56 | 4.07 | 0.17 | -0.05 | 0.38 | 0.13 | | | | |
| -TAU | | | | | 3.79 | 3.52 | 4.05 | 0.14 | -0.09 | 0.37 | 0.23 | | | | |
| BASIS-32 | 1.29 | 1.06 | | 1.52 | | | | | | | | 0.03 | -0.34 | 0.40 | 0.88 |
| -SRIT | | | | | 1.27 | 0.98 | 1.56 | -0.02 | -0.29 | 0.24 | 0.87 | | | | |
| -TAU | | | | | 1.24 | 0.93 | 1.55 | -0.05 | -0.34 | 0.23 | 0.72 | | | | |

PAM-13 = Patient Activation Measure (range from 0 to 100, an increase in scores indicates improvement).

RAS = Recovery Assessment Scale (range 24-120, an increase in scores indicates improvement).

BASIS-32 = The Behaviour and Symptom Identification Scale (range 0-128, a decrease in scores indicates improvement).

improve patient's activation. The study included mostly inpatients on their way to be discharged, and who had knowledge and skills after years of experience in mental health services. This may have contributed to higher activation level at baseline (>64, beginning to take action) and thus it might be more difficult to obtain further improvement in activation. Twenty of 26 participants used the SRIT contract for self-referral during the intervention period, which showed that they took action and responsibility for own health.

Due to lack of SRIT studies reporting patients assessed questionnaires one should be careful comparing other studies with the present. However, other intervention studies aiming to improve patient activation found improvement among patients with mental disorders [43,44], while another found no significant difference [45]. All studies had lower patient activation level at baseline than the present study.

The post-hoc test showing that the three SRIT participants who had a PAM score below the lowest activation level \leq 47 [34] at baseline, had significantly higher PAM compared to those in TAU after 12 months. However, an exploratory post hoc analysis can only be used for generating the hypothesis that SRIT is a better alternative for those with low activation. But the result is interesting in light of what Hibbard and Greene found in their review regarding evidence of patients' activation and health outcomes, (i.e. patients with low activation tend to improve their Patient Activation Measure most) [46], and that effective interventions might help those with lowest activity to be more

active [7]. One can imagine that a SRIT intervention can help those patients to become more actively involved in their own treatment by offering support, and possibilities which increase levels of activation and self-management [10].

RAS was stable over 12 months and no significant group differences were found. However, there was a significant withingroup improvement in one of the recovery factors for SRIT: "willingness to ask for help". This may indicate that those in the intervention group developed an increased confidence in obtaining mental health care on their own during the intervention period. This is an important aspect in the recovery-process [47–49]. Moreover, qualitative studies nested within the present RCT reported that SRIT participants talked more about how more active cognitive strategies were used, and expressed less resignation, hopelessness and powerlessness than TAU patients [20], and that SRIT patients increased their confidence and ability to cope [23]. Thus, these studies along with others [18] give some indication that SRIT may empower and promote self-determination. Two other interventions among patients with mental disorders aiming to improve recovery likewise found no effect on recovery [50,51].

We found no significant group differences on BASIS-32. Both group had relatively low baseline scores, and were stable after the intervention period. There was no evidence for any deterioration on symptoms and functioning as measured by BASIS-32. SRIT is reported to be safe for included patients

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| Ta | bl | ρ | 4 |
| | | | |

Linear mixed model, ITT analyses from baseline to 12 months, within and between each group adjusted for age*.

| Outcome | Mean at baseline | | | Means at 12-months | | | | groups, aseline to 12 | months | | Between groups, at 12 months | | | | |
|-----------------------|---------------------|--------|-------|-----------------------|----------------|----------------|--------------|--------------------------|--------------|--------------|---------------------------------|--------|------|------|--|
| | Mean | 95% CI | | Mean | 95% CI | | d | 95% CI | | р | d | 95% CI | | р | |
| PAM-13 SRIT TAU | 64.01 | 59.83 | 68.19 | 64.63 66.67 | 59.09 60.86 | 70.17 72.49 | 0.62 2.67 | -4.48 -2.73 | 5.72 8.07 | 0.81 0.33 | -2.05 | -9.22 | 5.13 | 0.58 | |
| RAS SRIT TAU | 3.69 | 3.50 | 3.88 | 3.83 3.87 | 3.59 3.62 | 4.07 4.12 | 0.14 0.18 | -0.07 -0.04 | 0.35 0.40 | 0.14 0.11 | -0.04 | -0.33 | 0.26 | 0.80 | |

PAM-13 = Patient Activation Measure 13 (range from 0 to 100, an increase in scores indicates improvement).

RAS = Recovery Assessment Scale 24 (range 24-120, an increase in scores indicates improvement).

SRIT = Self-referral to inpatient treatment.

TAU = Treatment as usual SRIT = Self-referral to inpatient treatment.

*Age is estimated with use of the mean value at baseline 40.43 and at 12 months 41.43.

Table 5

Model based mixed model ITT, from baseline to12 months, within and between each group on the sub scores in RAS-24 and BASIS-32.

| Outcome | | Means | baseline | 2 | Means | at 12 moi | nths | Within gr | oups from bas | Between groups at 12 months | | | | | |
|------------------|-------------|-------|----------|------|--------------|--------------|--------------|----------------|---|-----------------------------|--------------|-------|--------|------|-----|
| | | Mean | 95% C | I | Mean | 95% CI | | d | 95% CI | | р | d | 95% CI | | р |
| RAS –PCH | | | | | | | | | | | | | | | |
| | SRIT TAU | 3.51 | 3.27 | 3.75 | 3.62 3.72 | 3.32 3.40 | 3.91 4.03 | 0.10 0.20 | $-0.15 \\ -0.06$ | 0.35 0.47 | 0.42 0.13 | -0.10 | -0.45 | 0.25 | 0.5 |
| -WAH | SRIT | 3.97 | 3.71 | 4.23 | 4.35 | 3.99 | 4.71 | 0.38 | 0.01 | 0.76 | 0.05 | 0.09 | -0.42 | 0.59 | 0.7 |
| -GSO | TAU | | | | 4.26 | 3.88 | 4.65 | 0.30 | -0.10 | 0.69 | 0.14 | | | | |
| 000 | SRIT TAU | 3.99 | 3.76 | 4.21 | 4.18 4.11 | 3.89 3.80 | 4.47 4.41 | 0.19 0.12 | -0.07 -0.16 | 0.46 0.40 | 0.16 0.41 | 0.07 | -0.30 | 0.45 | 0.7 |
| -ROO | SRIT TAU | 4.12 | 3.89 | 4.35 | 4.17 4.20 | 3.88 3.89 | 4.47 4.51 | 0.05 0.08 | -0.20 -0.20 | 0.31 0.35 | 0.68 0.58 | -0.02 | -0.39 | 0.34 | 0.9 |
| -NDS | IAU | | | | 4.20 | 5.85 | 4.51 | 0.08 | -0.20 | 0.55 | 0.58 | | | | |
| | SRIT TAU | 2.89 | 2.57 | 3.21 | 3.21 2.87 | 2.78 2.40 | 3.65 3.33 | 0.32 -0.02 | $-0.11 \\ -0.48$ | 0.75 0.43 | 0.14 0.92 | 0.34 | -0.25 | 0.94 | 0.2 |
| BASIS-32 –REL | | | | | | | | | | | | | | | |
| | SRIT TAU | 1.42 | 1.16 | 1.68 | 1.31 1.36 | 0.95 0.98 | 1.67 1.75 | -0.11 -0.06 | $\begin{array}{c} -0.48 \\ -0.44 \end{array}$ | 0.25 0.33 | 0.54 0.77 | -0.06 | -0.55 | 0.44 | 0.8 |
| -DEP | | | | | | | | | | | | | | | |
| | SRIT TAU | 1.57 | 1.30 | 1.85 | 1.50 1.60 | 1.12 1.20 | 1.88 2.00 | -0.07 0.03 | $-0.45 \\ -0.38$ | 0.31 0.44 | 0.72 0.89 | -0.10 | -0.62 | 0.42 | 0.7 |
| -DLR | ino | | | | 1.00 | 1,20 | 2.00 | 0.05 | -0.58 | 0.44 | 0.05 | | | | |
| | SRIT | 1.68 | 1.41 | 1.96 | 1.74 | 1.37 | 2.11 | 0.06 | -0.29 | 0.41 | 0.74 | 0.27 | -0.22 | 0.75 | 0.2 |
| -IAB | TAU | | | | 1.48 | 1.09 | 1.87 | -0.21 | -0.58 | 0.17 | 0.28 | | | | |
| -IAD | SRIT | 0.58 | 0.42 | 0.75 | 0.58 | 0.37 | 0.79 | -0.01 | -0.19 | 0.17 | 0.93 | 0.13 | -0.12 | 0.38 | 0.3 |
| | TAU | | | | 0.45 | 0.23 | 0.67 | -0.14 | -0.33 | 0.05 | 0.16 | | | | |
| -PSY | | | | | | | | | | | | | | | |
| | SRIT TAU | 0.87 | 0.62 | 1.11 | 0.97 0.89 | 0.65 0.56 | 1.28 1.23 | 0.10 0.03 | -0.19 -0.28 | 0.39 0.33 | 0.49 0.87 | 0.08 | -0.33 | 0.48 | 0.7 |

RAS = Recovery Assessment Scale 24 (range 24–120, an increase in scores indicates improvement). PCH-personal confidence and hope, WAH-willingness to ask for help, GSOgoal and success orientation, ROO-reliance on others, NDS-no domination by symptoms.

BASIS-32 = The Behaviour and Symptom Identification Scale 32 (range 0–128, a decrease in scores indicates improvement).REL-relation to self and others, DEP-depression/ anxiety, DLR-daily living/role functioning, IAB-impulsive/addictive behaviour, PSY-psychosis.

[20,23]. However, severe mental disorders are complex, require support to manage deteriorations, and may require more complex interventions [52]. SRIT supports the legislation on patients' rights, and the medical ethical principles of doing good, autonomy, justice [53].

The current study has strengths and limitations that can affect the interpretation of the findings. This is the first randomized controlled study measuring the long-term effects of a SRIT contract. However, our findings should be interpreted with caution due to the relatively small number of participants. Although the sample size reached the predefined number, the standard deviation used in the power calculation (SD = 11) was lower than the one in the present study (SD = 16.7).

The non-significant main result could be due to the questionnaires used, which might not have covered the aspects that the patients found most important. All participants knew they would have a SRIT contract from the day they completed the 12- months score. They were happy to get a contract, which could have affected their scorings.

Recovery can be defined in various ways [54], and the method we applied may not have a sufficient scope to measure all sides of personalized recovery [55]. The participants were not systematically diagnosed using The Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I) [56], but were clinically diagnosed based on at least two years of previous contact.

4.2. Conclusion

There were no significant effects on patient activation, personal recovery or symptoms and functioning for patients having a SRIT contract compared to those with TAU, but both group maintained their baseline levels, after 12 months. An exploratory post hoc analysis generated a hypothesis that SRIT may be a better alternative for those with low activation. Additional research is needed to better understand the effects and potential of SRIT.

4.3. Practice implication

SRIT in community mental health services represents a supplement to promote user participation in decision-making, and to meet patients' rights.

Authors' contributions

IEOM collected, analyzed and interpreted data, contributed with the analyses, wrote and finished the manuscript. MLLC have contributed with the analyses and the manuscript. ØS have analyzed the main data and contributed in completing the manuscript. GHE, TMO, CBG, DØA, DB, MBR and AS have contributed to the design and completing of the manuscript. OML have contributed with the manuscript. All authors have read and accepted the final manuscript. LE has contributed with the design and the manuscript; unfortunately, he passed away in July 2016.

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