# Social recovery therapy for young people with emerging severe mental illness: the Prodigy RCT

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## Scientific summary

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# Scientific summary



## Background

Young people who have social disability associated with non-psychotic severe and complex mental health problems are an important group in need of early intervention. Their problems are often long-standing and evident from an early age. They have a high risk of long-term and serious mental health problems and social disability. Without intervention, the long-term prognosis is poor and the economic costs are large. There is a gap in the provision of evidence-based interventions for this group, and new approaches are needed. We aimed to evaluate a new approach to early intervention with young people with social disability and non-psychotic severe and complex mental health problems using social recovery therapy over a period of 9 months to improve mental health and social recovery outcomes, and to compare it with enhanced standard care.

## Objectives

To undertake a definitive randomised trial to determine the clinical effectiveness and cost-effectiveness of social recovery therapy compared with enhanced standard care in young people who present with social withdrawal and non-psychotic severe and complex mental health problems, and who are at risk of long-term social disability and mental illness.

The primary hypothesis was that, for young people who are socially disabled and have non-psychotic severe and complex mental health problems, social recovery therapy plus enhanced standard care would be superior to enhanced standard care alone in improving social recovery (as measured by hours in structured activity assessed on the Time Use Survey) over a 15-month follow-up period. Secondary hypotheses were, first, that social recovery therapy plus enhanced standard care would be superior to enhanced standard care alone in terms of cost-effectiveness and, second, that social recovery therapy plus enhanced standard care would be superior to enhanced standard care alone in effects on mental health symptoms (attenuated psychotic symptoms and emotional disturbance).

## Methods

This was a pragmatic, multicentre, single-blind, superiority randomised controlled trial. It was conducted in three sites in the UK: Sussex, Manchester and East Anglia. Participants were recruited between 2012 and 2017. Inclusion criteria were that participants (1) were aged 16–25 years; (2) had persistent social

disability operationalised as structured and constructive economic activity of < 30 hours per week and a history of social impairment problems lasting for at least 6 months; and (3) had severe and complex mental health problems operationalised as (a) meeting at-risk mental states for psychosis criteria, or (b) non-psychotic mental health problems scoring ≤ 50 on the Global Assessment of Functioning scale (indicating the presence of severe symptoms of at least two out of depression, anxiety, substance misuse, thinking or behavioural problems) with at least moderate symptoms (operationalised as a Global Assessment of Functioning score < 60) persisting for a period of at least 6 months. Exclusion criteria were current or historical psychosis, severe learning disability, presence of disease, physical problems, or non-English speaking to a degree that interferes with the capacity to consent to and participate in the research.

The sample size was 270 participants, providing 135 participants per trial arm. An effect size of 0.4 standard deviations was considered a minimum clinically significant benefit, with 270 participants providing > 90% power to detect this effect with a two-sided 5% significance level. Participants were randomised 1 : 1 using a web-based randomisation system and allocated to either social recovery therapy plus optimised treatment as usual (enhanced standard care) or enhanced standard care alone. The primary outcome was time use, namely hours spent in structured activity per week at 15 months post randomisation. Secondary outcomes assessed typical mental health problems of the group, including subthreshold psychotic symptoms, negative symptoms, depression and anxiety. Time use, secondary outcomes and health economic measures were assessed at 9 and 15 months. Maintenance of outcome was assessed in a separate study at 24 months. The main trial results were tested using general linear models, with site as a random factor, and adjusting for stratification variables and neurocognitive performance. Maintenance of gains was tested using available data at 24 months.

Three qualitative process evaluation substudies were conducted. The first captured participants' perspectives on their experiences of the research processes, including assessment involvement and contact with the research team. The second captured patient perspectives, but focused primarily on experiences of allocation, provision and involvement in social recovery therapy and enhanced standard care intervention. Both patient process evaluation substudies were interview-based, using thematic analytic methods, and were conducted by a sub-research team co-led by an independent qualitative researcher, user researcher and members of the trial team. The final process evaluation focused on social recovery therapy therapist experience of working with complex clients. This was an interview study using an Interpretative Phenomenological Analysis methodology and was led by trial team members who were not involved in the original inception of social recovery therapy or the present study.

## Results

In total, 942 young people were referred. From this group, 298 young people were not appropriate referrals, 194 young people were not interested in becoming involved in the research and six young people declined to consent. Therefore, 444 young people were assessed for eligibility, 174 of whom were not eligible, including 27 who did not complete the assessment process. Of the 270 randomised participants, there were 241 participants retained at 9 months, 235 participants at 15 months and 206 participants at 24 months.

We found no evidence that social recovery therapy was superior to enhanced standard care on the primary outcome of weekly hours spent in structured activity at 15 months (Time Use Survey) (treatment effect −4.44, 95% confidence interval −10.19 to 1.31). We found no evidence of significant differences between trial arms in secondary outcomes at the primary end point of 15 months: Social Anxiety Interaction Scale treatment effect −0.45, 95% confidence interval −4.84 to 3.95; Beck Depression Inventory-II treatment effect −0.32, 95% confidence interval −4.06 to 3.42; Comprehensive Assessment of At-Risk Mental States symptom severity treatment effect 0.29, 95% confidence interval −4.35 to 4.94;

or distress treatment effect 4.09, 95% confidence interval −3.52 to 11.70. Greater Comprehensive Assessment of At-Risk Mental States for psychosis scores reflect greater symptom severity. We found no evidence of significant differences at 9 or 24 months. Social recovery therapy was not estimated to be cost-effective.

On some dimensions there appeared to be mean differences favouring enhanced standard care over social recovery therapy plus enhanced standard care. However, the differences on the primary outcome and the majority of secondary outcomes did not meet the level for conventional significance, apart from social phobia and some subscales of negative symptoms at 15 months. At 24 months, mean differences on structured activity favoured enhanced standard care over social recovery therapy and enhanced standard care. Missingness of data was consistently higher in the enhanced standard care group than in social recovery therapy plus enhanced standard care group, and the bias and total amount of missingness of data increased over time. Although there were few data missing at 9 months (< 10%), at 15 months 20% of data on the primary outcome were missing and with a clear bias to greater missingness of data in the enhanced standard care group. At 24 months, > 30% data were missing and the amount of missingness of data in the enhanced standard care group was twice that in the social recovery therapy plus enhanced standard care group. It is plausible that differential missingness of data could bias results in favour of enhanced standard care, particularly at the later assessment stages. Although it is clear that there is no superiority for social recovery therapy, we are more cautious in concluding firmly that enhanced standard care alone was superior, even though there are trends in that direction.

There was a general pattern of large and clinically significant improvements over time in both the social recovery therapy plus enhanced standard care arm and the enhanced standard care-alone arm. There were large effect size gains in structured and constructive economic activity of > 10 hours per week in both arms. This is more than double the 4 hours constituting a clinically meaningful difference. There was a > 50% improvement in the rate of participants meeting diagnostic criteria for depression, panic, agoraphobia and social phobia in both groups and there were large effect gains in self-reported assessments of depression, social anxiety, hopelessness and schizotypal symptoms of paranoia and anomalous experiences, and negative symptoms. There were marked reductions in alcohol and drug use disorders.

The process evaluation suggested that participants valued both the research assessment process and social recovery therapy. Participants emphasised that social recovery therapy could be challenging to engage in and that the development of a positive therapeutic relationship with a social recovery therapy therapist was an essential aspect of the intervention. Participants emphasised, both in the research assessments and in social recovery therapy, the importance of discussing their experiences with another person. The process evaluation substudy with social recovery therapy therapists suggested that therapists could struggle with feelings of hopelessness in the context of therapy delivery with a group of young people characterised by ambivalence, a sense of being stuck and hopelessness. Nevertheless, adherence and competence data suggested that therapists delivered competent social recovery therapy, which was fully adherent to the therapy model in > 80% of cases.

## Conclusions

The key conclusion of this study is that there was no evidence for the clinical superiority of social recovery therapy over enhanced standard care for any outcome, nor was there evidence of the cost-effectiveness of social recovery therapy. Both intervention groups made large and clinically significant gains in time use and across the spectra of social and mental health problem outcomes. Available data suggested that these gains were maintained in both groups of participants. There was an evident effect of the social recovery therapy intervention on participant engagement.

It was very notable that participants in the enhanced standard care-alone arm typically reported combinations of case management, psychological therapy, employment support, social care and youth support. In addition, the majority of participants reported taking psychiatric medication; therefore, enhanced standard care did not reflect the absence of intervention. The key clinical implication of this trial is, therefore, that if young people with non-psychotic severe and complex mental health problems and social disability are offered systematic intervention, then large and important gains in social and mental health outcomes are likely to occur. These services must be equipped to be able to manage the severity and complexity evident in this group of young people.

Recommendations for research include:

- The capture of engagement as an outcome of intervention – social recovery therapy had a clear effect on engagement and engagement itself is an important predictor of outcome and target for intervention. Future research could explore putative mechanisms of increased engagement and endeavour to isolate the key components of social recovery therapy (or other interventions) that have an impact on this.
- The capture of outcomes in absentia – the identification and operationalisation of meaningful outcomes that can be measured in the absence of face-to-face assessment is an important development to facilitate evaluating beneficial interventions for young people who struggle to engage with in-person research and clinical interactions.
- Investigation of person-centred treatment for young people with emerging non-psychotic severe and complex mental health problems – the current study reports no differences in group-level average effects of enhanced standard care versus enhanced standard care plus social recovery therapy. Future research should investigate what works for whom: the necessary and sufficient components of treatment for young people with emerging non-psychotic severe and complex mental health problems and social disability. The identification of subgroups of young people with emerging non-psychotic severe and complex mental health problems and social disability who respond differently to treatment as usual, for example subgroups that may be 'treatment resistant' and thus in need of more specialised interventions, are important for further research.

## Trial registration

This trial is registered as ISRCTN47998710.

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### This report

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