Randomized controlled study of PR-ESSENCE - a problem-solving model for youth with challenging behavior in SiS youth homes.

Background

The ”Collaborative Problem Solving” (CPS) model was developed by psychologist Ross Greene, Harvard University, and is presently referred to as “Collaborative and Proactive Solutions”. The method is based on the theory that challenging behavior is due to lagging skills, especially in the areas of cognitive flexibility, frustration tolerance and problem-solving ability. With the model, adults and youth collaborate to analyze triggers for problematic behaviors, suggest possible problem solutions and strategies which may benefit both parties, and practice them systematically in everyday life.

The CPS model has been evaluated in US studies, and our research group performed a pilot study in Sweden for children with ADHD and Oppositional Defiant Disorder (ODD). Based on experiences, our team has since adapted the CPS-method to children with complex neurodevelopmental disorders. We use the term ESSENCE (Early Symptomatic Syndromes Eliciting Neuropsychiatric Examinations), an umbrella term for neurodevelopmental disorders in children, and we call our model PR-ESSENCE (Problem Resolution for ESSENCE).

The Gillberg Neuropsychiatry Centre (GNC) PR-ESSENCE trial 2014-2019

We recently conducted a randomized controlled trial (RCT) with 108 children and adolescents aged 5-18 years, with ESSENCE and challenging behaviors (submitted). The active group received PR-ESSENCE training for 10 weeks. The control group received ”treatment as usual (TAU)” for 10 weeks (that is information, support and individualized treatment according to standard treatment guidelines), followed by 10 weeks of PR-ESSENCE-training. The 10-week PR-ESSENCE treatment period included a visit once a week when parents and children met the therapists to learn the method and to collaborate in finding problem solution strategies, which the families then practiced at home between visits. Primary outcome was Clinical Global Impression-Improvement (CGI-I) ratings by independent blinded assessors, based on all available information. Outcome data were collected at baseline, post-treatment/control period, after 6 months and 1 year. Clinical response was defined as being much or very much improved on the CGI-I. At post-treatment 51.4% in the active group were responders, compared to 5.6% in the control group. After 1 year 63% of all were responders, which suggests a long-term consolidated learning and change in relations and behavior patterns.

The PR-ESSENCE SiS youth home trial 2021-2024

Design

Inspired by the results of the GNC trial described above we plan to test the method in an RCT with similar design for youth with challenging behaviors in SiS Youth Homes. During three years 60-70 youth will be included in the trial. They will be randomized 1:1 to active group or control group. The active group will receive PR-ESSENCE training for 10 weeks. The control group will receive ”treatment as usual (TAU)” for 10 weeks, followed by 10 weeks of PR-ESSENCE treatment.

Research questions

Can the PR-ESSENCE-method reduce problem behaviors, solve problematic situations, and improve psychological well-being and self-image for youth resident in SiS Youth Homes?

Inclusion criteria

1. Youth with challenging behavior who are placed (at least 3 months) at SiS Youth Home for boys (Nereby), and girls (Björkbacken).
2. Age according to SiS framework (12-17 years).
3. Intellectual function in the normal range, according to WISC-test and clinical judgment.

4. Broset Violence Checklist (BVC) - ratings, at least 5 points of problem behaviors per week (points per week are calculated from the daily ratings during 2 weeks before the screening period, and the score of the week with most points is used for inclusion).
5. YLS/CMI domain 7 (behavior problems) score indicates medium to high risk
6. Medication allowed if stable at least one month before baseline and during the trial.

Exclusion criteria

1. Intellectual disability, bipolar disorder, psychosis, substance use, or other unstable psychiatric or medical condition which could entail risk or limit participation in the trial.

Outcome measures

All outcome data will be collected at baseline, at post-treatment/control period follow-up, and as long-term follow-up before the youth leaves the SiS home (this time point may vary several months).

Ratings by independent blinded assessor

Clinical Global Impression-Improvement (CGI-I): Scale for rating of global improvement or worsening of problems/symptoms (score range 1-7; 1 very much improved, 7 very much worse) (Guy 1976).
Clinical Global Impression-Severity (CGI-S): Scale for rating of global problem/symptom severity (score range 1-7; 1 no problems, 7 extreme problems) (Guy 1976).

Ratings by contact persons

Broset Violence Checklist (BVC) - ratings of daily problem behaviors
SNAP – IV – Swanson, Nolan and Pelham scale. Rating scale for ADHD- and oppositional symptoms (Swanson 1992).
ECBI - Eyberg Child Behavior Inventory – rating scale for challenging behaviors (Eyberg & Pincus 1999).
RPQ - Relationship Problems Questionnaire – rating scale for relationship problems (Minnis et al 2002)

Youth self-ratings

BYI - Beck Youth Inventories - interview about symptoms of depression, anxiety, irritability, challenging behavior, self-image (Beck et al 2005).

Screening (at the youth home during 2 weeks before baseline)

Informed consent from youth and parents/caregiver (collected by Coordinator)
Psychologist assessments:

- YLS/CMI (standard assessment for all youth at arrival to SiS home).
- DSM-5-diagnostic screening for psychiatric problems
- WISC-V test of intellectual level

Youth self-rating (with psychologist):

- BYI for assessment of psychological well-being and self-image

A-TAC-interview: Parents/caregivers interviewed by therapist to screen for neuropsychiatric problems
BVC-ratings of problem behaviors, made daily during 2 weeks by contact persons at the youth home (ward and school). Results are used as inclusion criterium

Screening visit at GNC – or videolink:

Coordinator and contact persons from the youth home together with the GNC *blinded assessor* assess the screening results and inclusion/exclusion criteria.

Randomisation

Computer-generated unstratified block-randomisation (blocks of 4-8 youth) 1:1 to treatment or control, is performed by independent project leader

Primary outcome

- CGI-I rated by blinded assessor

Secondary outcomes (change from baseline measured with the following instruments):

- CGI-S rated by blinded assessor
- Ratings by the youth's contact person:
  - BVC (number/intensity of problem situations)
  - SNAP-IV (ADHD and oppositional symptoms)
  - ECBI (challenging behaviors)
  - RPQ (relationship problems)
- BYI (youth self-ratings)
- Therapist-ratings with the Problem Rating Scale (measures how many problem situations could be wholly or partially solved).

Active group: Contact person and youth learn and practice the method at weekly visits with therapist for 10 weeks, and practice problem solution strategies in everyday life between visits. Therapists will be given supervision and support once monthly from therapists in our GNC research team.
Control group: Receives "treatment as usual" during the 10-week control period, and thereafter 10 weeks of PR-ESSENCE-training.

Continuous evaluations during the trial

- *BVC*-ratings of problem behaviors will be made daily during the whole trial, by contact persons at the youth home (ward and school). Weekly results will be collected.
- With the Problem Rating Scale, the therapists will at each visit rate the number of problem situations which have been wholly or partially solved.

Statistical plan
Sample size calculation indicates that with power 0·80 and signi ficance level of ·05, a sample of 52 participants would be required to detect an effect size (Cohen's d) of 0.7, which may be considered as a clinically meaningful effect. Previous research has shown larger effect sizes on the primary outcome measure CGI-I. Primary and secondary efficacy analyses will be performed on all randomized subjects (Intention-to-Treat (ITT) population) with baseline values carried forward to endpoint for dropouts, on the Full Analysis Set (FA set) defined as all randomized subjects with any baseline and any end of treatment measurements, and on the Per Protocol population (subjects who completely followed the protocol). Analyses of covariance, covarying for baseline values, will be used to compare posttreatment assessment scores in the PR-ESSENCE versus control groups. For comparison between the groups Mantel-Haenszel chi-square test will be used for ordered categorical variables, Fisher's exact test for dichotomous variables and Pearson chi-square for non-ordered categorical variables. For dichotomous variables the risk difference with 95% CI and the risk ratio with 95% CI will be presented. Effect Sizes (ES) will be calculated as the difference in mean scores between PR-ESSENCE group and controls, divided by the pooled standard deviation. The distribution of continuous and interval scaled variables will be reported as mean, SD, median, minimum and maximum and distribution of categorical variables as numbers and percentages.

Dissemination
Our research team will collect and analyze all data, write research reports, publish the study results on group level in international journals, and present results on national and international conferences. Education and supervision on the method can be provided to other SiS youth homes on demand.

Future perspectives
The GNC trial provided new knowledge about solutions for behavior problems and conflict management. We hope that PR-ESSENCE training in SiS Youth Homes can give long-term improvements in self-regulation abilities and conflict solutions, and thereby prevent challenging, disruptive and antisocial behaviors. If lasting improvements in problem-solving abilities and

interaction could reduce violence, drug use and criminality, this would give large psychological and economic gains for families and society.

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