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Evaluation of Functional Family Therapy (FFT) in Norway

Submission date	Recruitment status	[ ] Prospectively registered
26/04/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/05/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/05/2013	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Background and study aims:
Serious behavior problems among adolescents are of great concern in Norway. If left untreated, con behavior problems can result in school dropout, foster care, alcohol/drug abuse, criminal involvement, and psychological disorders. Developing efficient ways to avoid these problems therefore have high priority. Functional Family Therapy (FFT) is a family-based program that has been applied successfully in treating a range of high-risk youth and their families. However, uncertainty remains about how well FFT would translate in to our culture. In addition, further research is needed to find out the reasons for treatment failure/success (moderators) and how FFT works (the mechanisms). The primary aim of the study is to find out whether FFT works, compared to general family counseling, in decreasing antisocial behavior and in increasing social functioning.

Who can participate?
Participants are families with youth between 11 and 19 years of age, referred from the municipal Child Welfare Services to the corresponding specialist services for serious behavioral problems.

What does the study involve?
The participants are randomly allocated to one of two groups. One group undergoes FFT and the other gets a general family counseling. FFT is a step-by-step counseling program which concentrates on retaining the youth in the program, motivation, assessment and bringing behavioral changes. For mild cases, the counseling can last for 8 to 12 sessions and for severe cases, up to 30 hours.

What are the possible benefits and risks of participating?
There are no known risks or side effects from either FFT or general family counseling.

Where is the study run from?
The three FFT sites in Norway (Skien, Trondheim, and Stavanger) will participate in the present study.

When is the study starting and how long is it expected to run for?
The trial starts in May 2013 and is expected to run for at least four years.

Who is funding the study?
The Norwegian Center for Child Behavioral Development (Norway).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Evaluation of Functional Family Therapy (FFT) in Norway: one-year follow-up of a randomized trial investigating the effect of Functional Family Therapy (FFT) versus general family counseling by the family counseling service for externalizing disorders in adolescents

Acronym
FFT

Study objectives
The primary aim is to determine the effectiveness of Functional Family Therapy in key outcome variables compared to family counseling by the family counseling service, six months after treatment is started (post-assessment) and 18 months after treatment is started (follow-up assessment). FFT views clinical problems multisystemically, both within systems of the family relational units and between the family and its environmental and social context. This principle is based on growing evidence that the problems of these youths are best understood by looking at their individual behavior, nested within the family, which is part of a broad community system (Sexton & Alexander, 2005).
The key outcome variables are parent- and teacher-rated externalizing problems, social skills, and youth-reported delinquency. Other outcome variables include parent- and teacher-rated internalizing and total problem scales, family conflicts, family cohesion, treatment integrity, and substance abuse (alcohol and drugs).

Primary research questions
1. How effective is Functional Family Therapy, compared to general family counseling, in reducing problem behavior and increasing social competence in the family?
2. How effective is Functional Family Therapy, compared to general family counseling, in reducing problem behavior, and increasing social competence and academic performance at school?
3. How effective is Functional Family Therapy, compared to general family counseling, in reducing contact with antisocial friends and increasing contact with prosocial friends?
4. How effective is Functional Family Therapy, compared to general family counseling, in reducing negative communication and conflicts and increasing positive communication, social support, cohesion, and the quality of relations and conflict tactics in the family?
5. Is FFT successful in preventing out-of-home placement and reducing rearrests?
The secondary aims are to investigate possible mechanisms and moderators of effects:
1. To examine communication in the family, family cohesion, relations with parents, and social support as possible mediators of effects.
2. To examine personality traits i.e., CU, BIS/BAS, diagnosis, gang membership, implementation quality, therapeutic alliance, treatment integrity, SES, single parenthood, gender, and age of onset as possible moderators of effects

Ethics approval required
Old ethics approval format

Ethics approval(s)
The project has been approved by The National Committee for Medical and Health Research Ethics (NEM)
Date of approval 02.11.2010 and 02.10.2012
Reference number 2010/497

Primary study design
Interventional

Study design
Randomized controlled trial with a follow-up design

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Behavioral disorder/behavioral problems

Interventions
The experimental arm consists of Functional Family Therapy (FFT). The therapy targets youth between the age of 11 and 19 from various ethnic and cultural groups. The therapy is a short-term intervention including, on average, 8 to 12 sessions for mild cases and up to 30 hours of direct service for more difficult cases (Mørkrid & Christensen, 2007). Working with the families of delinquent adolescents, FFT aims to: 1) Reduce defensive communication patterns, 2) Increase supportive interactions, and 3) Promote supervision and effective discipline (Brosnan & Carr, 2000). According to Alexander, Pugh, Parsons, and Sexton (2002), FFT effectiveness derives from emphasizing factors that enhance protective factors and reduce risk, including risk of treatment termination. To accomplish these changes in the most effective manner, FFT is a phasic program with steps that build on each other. These phases consist of the following:

1. Engagement, designed to emphasize within youth and family factors that protect youth and families from early program dropout
2. Motivation, designed to change emotional reactions and beliefs, and increase alliance, trust, hope, and motivation for lasting change
3. Assessment, designed to clarify individual, family systems, and larger system relationships, especially the interpersonal functions of behavior and how they relate to change techniques
4. Behavior change, which consists of communication training, specific tasks, and technical aids, basic parenting skills, problem-solving and conflict management skills, contracting, and response-cost techniques
5. Generalization, during which family case management is guided by individualized family functional needs, their interface with community-based environmental constrains and resources, and the alliance with the FFT therapist
Control: The comparison group consists of an active treatment alternative from the family counseling service

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The assessment of the key outcome measure in both the intervention and comparison group will be conducted before treatment and 6month after the initiation of the intervention, and again 12 months following the second assessment.
Problem behavior and social competence
1. Parent reports
1.1 Child Behavior Checklist, Parent version. The Child Behavior Checklist (Achenbach & Rescorla; CBCL/6-18) will be completed by parents. The instruments have been standardized and validated in Norwegian norming studies (Nøvik, 1999) and in clinical trials (e.g., Ogden & Amlund-Hagen, 2006). The externalizing scales, aggression and delinquency, the attention problems scale, the internalizing broadband syndrome scale, and the total problem scale, will be used in the present study
1.2. The SNAP-4- Rating scale (Swanson, Nolan, & Pelham, 1983) will be used to measure inattention and hyperactivity/impulsivity, and ODD. SNAP uses items from the DSM-5 criteria
1.3. The Connors Index Questionnaire (Connors, 1968). A general index of childhood problems
1.4. Social Skills Rating System. The Social Skills Rating System (SSRS, Gresham & Elliott, 1990) is a standardized, multi-rater instrument that assesses social skills in children and youth. The parent version covers cooperation, assertion, responsibility, and self-control. The teacher version measures cooperation, self-control, and assertion. Higher scores indicate greater social skills.
2. Teacher reports
2.1. The Teacher Report Form (TRF/6-18; Achenbach & Rescorla, 2001) obtains teacher's reports of children's academic performance, adaptive functioning, and behavioral/emotional problems
2.2. SNAP-4 and The Connors Index Questionnaire (see parent report)
2.3. The Social Skills Rating System (SSRS, Gresham & Elliott, 1990; Ogden, 2003) (see parent report)
3. Youth self-report
3.1. To tap covert and overt antisocial behavior that pertains to violent offending, general delinquency, and status offenses, we will use the Self-Reported Delinquency scale (SRD; Huizinga & Elliott, 1986)

4. Archival data
4.1. Archival data pertaining to arrest/recidivism are collected after 18 months and 36 months
4.2. Placement outside the home. The youths placement is measured using two parent-reported items that ask where the youth was living 1) at the time of the assessment and 2) most of the previous 12 months.

Key secondary outcome(s)

A standard demographic questionnaire will be administered to the parents. This questionnaire obtains items assessing annual family income, parents/target child age, civil status, gender, education level, receiving welfare or not, target childs onset of antisocial behavior, treatment history, ethnicity, family size, and history of out-of-home placement and arrests.
1. Parent reports
1.1. Parental mental distress will be measured with a Norwegian version of the parental mental distress 8-item version of the Hopkins Symptom Check List (SCL-8; Derogatis, Lipman, Rickels, Uhlenhuth, & Covi, 1974; Flink et al., 1995)
1.2. The degree of commitment, help, and support family members provide for one other (the Cohesion scale) and the amount of openly expressed anger and conflict among family members (the Conflict scale) will be measured with the Family Environment Scale (FES; Moos & Moos, 2002)
1.3. The Norwegian version of the Conflict Tactics Scales (CTS; Straus, 1979; CTS2; Bendixsen, 2005; Strauss, Hamby, Boney-McCoy, & Sugerman, 1996) will be implemented to measure the occurrence of several methods of conflict resolution used by the caretakers
1.4. The Inventory of Callous-Unemotional Traits (ICU) will be used to measure emotional dysregulation. These traits have proven to be important for designating a distinct subgroup group of antisocial and aggressive youth. The ICU has three subscales: callousness, uncaring, and unemotional.
1.5. The Alcohol Use Disorders Identification Test (AUDIT, Babor et al., 2006) will be used to measure parents alcohol consumption
1.6. The Alabama Parenting Questionnaire (APQ) will be used to measure several dimensions of parenting that have proven to be important for understanding the causes of conduct problems and delinquency in youth: positive reinforcement, parental involvement, inconsistent discipline, poor monitoring and supervision, and harsh discipline
1.7. The Unidimensional Relationship Closeness Scale (URCS; Dibble, Levine, & Park, 2011) will measure the closeness of social and personal relationships
1.8. The Inclusion of Other in the Self scale (IOS, Aron, Aron, & Smollan, 1992) will be used as a measure of self-other inclusion and relationship closeness
1.9. The Influence in Families Questionnaire (IFQ; Migerode, Femke, Buysse, Ann, Maes, Bea, De Mol, Jan, 2012) will be used to assess interpersonal influence in families
1.10. The Interpersonal Sense Of Control measure (ISOC; Cook, 1993) will be used to measure family members' beliefs about their ability to influence one another. Three reliable dimensions have been identified in the ISOC measure: (a) effectancea feeling of personal control in the relationship, (b) acquiescencethe belief that one is controlled by the partner, and (c) fatethe belief that relationship outcomes are due to fate, chance, or unknown factors.
1.11. Client Outcome Measure; (COM-P), is an FFT-specific family-reported post-treatment change indicator. The parent-version asks for client-perceived changes in areas like general well-being, problem behavior, communication, conflicts, co-operation, monitoring, parenting skills, youth alcohol-/drug-use and school attendance.
1.12. Hours in therapy will be measured using one parent-reported and one therapist-reported item at post assessment
1.13. Family satisfaction survey. Caregivers will complete the family satisfaction survey (Lubrecht, 1992) to indicate their extent of satisfaction with the service they received. Only at

post assessment
2. Teacher reports
2.1. The Inventory of Callous-Unemotional Traits (ICU, Frick, 2003) will be used to assess emotional dysregulation. These traits have proven to be important for designating a distinct subgroup group of antisocial and aggressive youth. The ICU has three subscales: callousness, uncaring, and unemotional.
3. Youth self-report
3.1. Child anxiety and depression (SCL-8; Strand, Dalgard, Tambs, & Rognerud, 2003) will be measured with the short version of the SCL, the SCL-8, a self-administered instrument designed to measure psychological distress, particularly anxiety and depression
3.2. Bjørnebekks (2009a) youth version of Carver and Whites BAS/BIS scales will be used to assess sensitivity in the behavioral inhibition system (BIS) and the behavioral approach system (BAS)
3.3. The Inventory of Callous-Unemotional Traits (ICU) will be used to assess emotional dysregulation
3.4. To assess adolescents perceptions of the positive and negative affective/cognitive dimensions of relationships with parents and close friends, we will use the Inventory of Parent and Peer Attachment (IPPA, Armsden & Greenberg, 1987)
3.5. To assess the youths positive psychological well-being, we will use the WHO 5 Wellbeing index (World Health Organization, 1998)
3.6. Social support will be measured with a Norwegian version of the Child and Adolescent Social Support Scale (CASSS; Malecki & Demaray, 2002)
3.7. The Bergen Questionnaire on Antisocial Behavior (Olweus & Kaufmann, 1989) will measure relations with and attachment to parents early in life
3.8. The Gang Membership Questionnaire (Bjørnebekk & Bjørnebekk, 2010) will measure youths gang membership
3.9. We will use the Oregon Healthy Teens Survey (OHS), the Personal Experiences Inventory, and the Alcohol Use Disorders Identification Test (AUDIT) as measures of the youths alcohol and substance use
3.10. Angry Aggression scales (Bjørnebekk & Howard, 2012) will be used to assess four violence types, each associated with the achievement of a particular goal, with a particular affective state (positive or negative), and a particular constellation of emotions: fear and distress (in the case of Aversive/Impulsive); spite and vengefulness (in the case of Aversive/Controlled); exhilaration and excitement (in the case of Appetitive/Impulsive); and pleasant anticipation (in the case of Appetitive/Controlled)
3.11. Client Outcome Measure (COM- A). The adolescent-version asks for client-perceived changes in areas like general well-being, problem behavior, communication, conflicts, monitoring and parenting skills
3.12. The Alabama Parenting Questionnaire (APQ) will be used to measure the youths perception of their parents use of positive reinforcement, parental involvement, inconsistent discipline, poor monitoring and supervision, and harsh discipline
3.13. The Unidimensional Relationship Closeness Scale (URCS; Dibble, Levine, & Park, 2011) will measure the closeness of social and personal relationships
3.14. The Inclusion of Other in the Self scale (IOS, Aron, Aron, & Smollan, 1992) will be used as a measure of self-other inclusion and relationship closeness
3.15. The Influence in Families Questionnaire (IFQ; Migerode, Femke, Buysse, Ann, Maes, Bea, De Mol, Jan, 2012) will be used to assess interpersonal influence in families
3.16. The Interpersonal Sense Of Control measure (ISOC; Cook, 1993) will be used to measure family members' beliefs about their ability to influence one another. Three reliable dimensions have been identified in the ISOC measure: (a) effectancea feeling of personal control in the relationship, (b) acquiescencethe belief that one is controlled by the partner, and (c) fatethe belief that relationship outcomes are due to fate, chance, or unknown factors

3.17. The Norwegian version of the Conflict Tactics scales (CTS; Straus, 1979; CTS2; Bendixsen, 2005; Strauss, Hamby, Boney-McCoy, & Sugerman, 1996) will be implemented to measure the occurrence of several methods of conflict resolution used by the youth and primary caretaker
4. Therapist
4.1. The therapist satisfaction survey (Lubrecht, 1992)
4.2. Organizational climate will be assessed using clinician reports on an adaptation of the Psychological Climate Questionnaire (PCQ; Glisson & Hemmelgarn, 1998)
4.3. The Implementation Component Questionnaire (ICQ; Ogden et al., 2012) will be used to measure implementation components
4.4. Therapist Outcome Measure (TOM) It asks for therapist assessment in areas like general well-being, problem behavior, communication, conflicts, co-operation, monitoring and parenting skills
5. FFT Team:
5.1. The youths risk, need, and responsivity factors will be measured with the Youth Level of Service Case Management Inventory (YLS/CMI; Hoge, Andrews, & Leschied, 2002)
6. Within-intervention assessment
7. Assessed monthly in a telephone interview
8. Telephone interview Parents
8.1. The Counseling Process Questionnaire (CPQ) is a 20-item instrument measuring family experiences in family therapy. The CPQ is designed to tap into client experiences that would be expected in each phase of FFT (six questions measure experiences that would be expected in each phase) and assess family members perceptions of the therapeutic process, therapeutic progress, and the therapeutic alliance. Two additional questions measure the degree of global change from the client perspective
8.2. The basic psychological need satisfaction will be measured with the Basic Psychological Need Satisfaction Scale (Halvari, Halvari, Bjørnebekk, & Deci, 2010)
8.3. In accordance with Dekovic et al. (2012), parental sense of competence will be measured with three items from the Parent Stress Index (Abidin, 1983)
8.4. The Alabama Parenting Questionnaire-Short Form (APQ-SF) is a nine-item measure of parenting style. The items are based on the three main structures of the parent (APQ) scale: positive parenting, inconsistent discipline, and poor supervision. The APQ-SF can be used by anyone wishing to measure parental practices regarding disruptive behavior (Elgar, Waschbusch, Dadds, & Sigvaldason, 2007).
8.5. Therapeutic alliance. Therapeutic alliance will be completed by the Working Alliance Inventory 12-item Short Form (WAI-S; Tracey & Kokotovic, 1989). Responses are collected from the primary caregiver. The sum score is used as a global measure of therapeutic alliance. The therapeutic alliance: (a) agreement on the tasks of therapy, (b) agreement on the goals of therapy, and (c) development of an affective bond.
8.6. The Brief Problem Monitor-Parent (BPM-P; Achenbach, McConaughy, Ivanova, & Rescorla, 2011) will be used to measure the youths Internalizing, Attention, and Externalizing problems over the previous 14 days
8.7. Four items from the SRD will be used to measure problem behavior at home the previous 14 days
8.8. We will ask five questions about the youths drug and alcohol use
9. Telephone interview Youth
9.1. The Alabama Parenting Questionnaire-Short Form (APQ-SF) is a nine-item measure of parenting style. The items are based on the three main structures of the parent (APQ) scale: positive parenting, inconsistent discipline, and poor supervision. The APQ-SF can be used by anyone wishing to measure parental practices regarding disruptive behavior (Elgar, Waschbusch, Dadds, & Sigvaldason, 2007).
9.2. Therapeutic alliance. Therapeutic alliance will be completed by the Working Alliance

Inventory 12-item Short Form (WAI-S; Tracey & Kokotovic, 1989). Responses are collected from the youth. The sum score is used as a global measure of therapeutic alliance.
9.3. The basic psychological need satisfaction will be measured with the Basic Psychological Need Satisfaction Scale (Halvari, Halvari, Bjørnebekk, & Deci, 2010)
9.4. The Counseling Process Questionnaire (CPQ) is a 20-item instrument measuring the family experiences in family therapy. The CPQ is designed to tap into client experiences that would be expected in each phase of FFT (six questions measure experiences that would be expected in each phase). Two additional questions measure the degree of global change from the clients perspective.
9.5. We will use the Oregon Healthy Teens Survey (OHS) as a measure of the youths alcohol and substance use
9.6. The Brief Problem Monitor-Parent (BPM-Y; Achenbach, McConaughy, Ivanova, & Rescorla, 2011) will be used to measure the youths Internalizing, Attention, and Externalizing problems over the previous 14 days
9.7. We will use four scales from the SRD (Elliott & Huizinga, 1983) to measure how many times the previous 14 days the youth have engaged in status offenses, violent offenses, destruction of property, and property offenses
10. Treatment integrity:
10.1. Program success is strongly related to whether the intervention is fully implemented and whether its fidelity is strictly monitored and demonstrates acceptable levels indicative of model replication. Threats to fidelity include deliberate non-compliance by staff, inadequate training, and program drift (Hollin, Epps, & Kendrick, 1995). In FFT, there are several sources for assessing model fidelity. Previous evaluation studies and standard implementation QA procedures rely on the judgment of clinical supervisors who perform "adherence/fidelity ratings" of therapists' work in topical issues each week. They will, in this study, supply three fidelity ratings per family completing therapy. In addition, client assessment of fidelity will be collected through client reports of treatment alliance from every first and second session of each treatment phase (totaling 6 reports per completed treatment), and the aforementioned CPQ-measure collected through monthly telephone interviews. Thirdly, FFT-therapists conduct a self-evaluation of treatment adherence and competency after each therapy session. Lastly, therapy conversations with families are recorded on video, and will be used as a fourth source for assessing treatment integrity. In this study, there will be videos of selected therapy sessions at the beginning, middle, and end of treatment. Video recordings will be analyzed so that the therapists' work can be scored in relation to the criteria for the FFT, and given a score for treatment integrity.

Completion date
28/05/2017

Eligibility

Key inclusion criteria
1. Youth who have committed crimes and at risk of committing more crimes
2. Youth who show aggressive and violent behavior, vandalism, and serious rule violation at home, in the community, or at school (conduct disorder)
3. Youth who are at least 11 years of age, but younger than 19
4. Immediate danger of placement outside the home
5. Truancy or problems at school related to behavior problems
6. Youth who display problem behavior at school or toward parents around school issues
7. Youth who display verbal aggression or verbal threats about hurting others related to the problems above
8. Youth who exhibit drug abuse related to the problems above

9. Youth who display problem behavior that makes drug abuse possible or in relation to parents when they communicate about or intervene in the youth's drug abuse
10. Youth who abuse drugs after displaying problem behavior
The FFT target group includes youth who are at risk of developing the kind of serious behavior problems described above. Youth at risk will be defined as having a score on the Youth Level of Services (YLS) of 9 (nine) or more, thus in the medium-, high- or very high-risk categories.
YLS has a four-category risk rating of low (0 to 8), medium (9 to 22), high (23 to 34), or very high (35 to 42).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Youth living by themselves, or youth who lack a primary caregiver
2. Youth who are autistic, acute psychotic, or in acute danger of committing suicide
3. Homes that pose a threat to the therapists life or safety
4. Cases that are still under assessment/investigation by the local child welfare services
5. Other services or treatments have been initiated that might interfere with the treatment

Date of first enrolment
17/05/2013

Date of final enrolment
28/05/2017

Locations

Countries of recruitment
Norway

Study participating centre
Postbox 7053
Oslo
Norway
0368

Sponsor information

Organisation
Norwegian Center for Child Behavioral Development (Norway)

Funder(s)

Funder type
Research organisation

Funder Name
The Norwegian Center for Child Behavioral Development (Norway)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration