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A pilot study of a couple–based intervention in the antenatal and early postnatal period to reduce discord

Submission date
29/04/2020

Recruitment status
No longer recruiting

Registration date
01/05/2020

Overall study status
Completed

Last Edited
22/09/2021

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Although some conflict and discord is a normal feature of any couple relationship, research shows that some kinds of discord and conflict between parents can be harmful to infants and children. This project aims to develop and pilot the use of a brief couple-focused intervention addressing inter-parental discord/conflict in the antenatal and early postnatal period.

Who can participate?
Couples aged 18 years or older, expecting their first baby, willing and able to take part in the study.

What does the study involve?
Couples expecting their first child will be approached in the maternity departments of the Royal Free Hospital and University College Hospital. Those who meet eligibility criteria and agreed to participate will be randomly assigned to the intervention group or to usual care but with visits from the research team to collect data on outcome measures. Those allocated to the experimental group will be offered a package of three sessions antenatally and two in the early postnatal period. The sessions will be offered at the Tavistock clinic or, if preferred, at home. The aim of the intervention is to address any areas of conflict/discord within the couple relationship in the context of the couple's transition to parenthood. Data on outcome measures is collected during short visits from a researcher at the start of the study and again when the baby is six months old. Data will be also collected remotely approximately 6 weeks after the baby's birth. Outcomes include the impact on the couple relationship, inter-parental conflict strategies, parent mental health, parent alcohol use and child development, measured using questionnaires.

What are the possible benefits and risks of participating?
Couples therapy is a 'talking treatment', so there were no physical risks to participants. Participants were advised that if they experienced distress through participating in the study (irrespective of treatment allocation), they should make contact with a member of the research team, who would work to provide appropriate support for the participant and/or their partner.

In terms of benefits, it was anticipated that those receiving the therapy would show reduced levels of conflict and better relationship satisfaction across the transition to parenthood. For both treatment and control groups, involvement in the study was expected to have possible benefits by alerting couples that an increase in discord was to be expected across the transition to parenthood.

Where is the study run from?
1. Royal Free Hospital (UK)
2. University College Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2006 to November 2009

Who is funding the study?
Mental Health Foundation (UK)

Who is the main contact?
Dr Rob Senior, rsenior@tavi-port.nhs.uk
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Inter–parental discord: A pilot study of a couple–based intervention in the antenatal and early postnatal period to reduce discord

Study objectives
Parents who receive the intervention will report better relationship quality, reduced inter-parental conflict, improved parent mental health, and fewer reported child temperamental difficulties, compared to those receiving treatment as usual across the transition to parenthood.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/04/2007, Camden and Islington Community Local Research Ethics Committee (Room 3/14, Third Floor, West Wing,
St. Pancras Hospital, 4 St. Pancras Way, London, NW1 0PE; +44 (0)207 530 3799), ref: 07/Q0511/3

Study design
Multi-centre parallel randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Inter-parental conflict during the perinatal period in couples becoming first-time parents

Interventions
Participants will be randomly allocated to receive TMT or TAU.

TMT: Three sessions of couples therapy were offered in the antenatal period, and two in the early postnatal period. The intervention was delivered by three experienced couple psychotherapists based at the Tavistock and Portman NHS Foundation Trust and the Royal Free Hospital. The intervention was developed for the purpose of this study, based on the extant

literature. Intervention content took a psycho-educational and solution-focused approach to examining the impact of inter-parental conflict on child development, and exploring ways to address it during the transition to parenthood. The couple's conflict management approaches were explored, and where appropriate, couples were helped to find alternative strategies. All sessions involved both members of the couple.

TAU: Usual care with no specific psychosocial intervention.

Those in the treatment group had five therapy sessions with a senior psychotherapist, either at home or at the Tavistock Clinic. The first session took place at 30 weeks of pregnancy, the second at 36 weeks, the third 12 weeks after the birth, the fourth 16 weeks after the birth, and the fifth 20 weeks after birth.

Couples completed outcome measures at the first research visit (conducted at approximately 28 weeks into the pregnancy), and at the second research visit when the child was 6 months old. In addition, couples returned a postal questionnaire 6 – 8 weeks after the birth of the baby.

Randomisation was conducted by an offsite statistician based at Leeds Clinical Trials Unit with no other contact with the trial. Allocation concealment was facilitated using sequentially numbered sealed envelopes for consecutive and eligible study participants. The researchers were not blinded to allocation condition, as they were responsible for communication of the allocation to participants at the first research visit (subsequent to completion of questionnaires), and managing any disappointment that it triggered.

Intervention Type
Behavioural

Primary outcome(s)
Collected at baseline (after the 20 week scan), approximately 6 weeks after the birth of the infant, and when the infant was six months old:
1. Relationship quality in cohabiting couples measured using the Dyadic Adjustment Scale
2. Conflict management approaches measured using the Revised Conflict Tactics Scale

Key secondary outcome(s))
Collected at baseline (after the 20 week scan), approximately 6 weeks after the birth of the infant, and when the infant was six months old. The Bates Infant Characteristic Questionnaire was collected only at the two time-points after the child's birth.
1. Mood symptoms during pregnancy and postpartum measured using the Edinburgh Postnatal Depression Scale
2. Symptoms of depression (7 items) and anxiety measured using the Hospital Anxiety and Depression Scale
3. Alcohol disorders and hazardous alcohol intake measured using the Alcohol Use Disorders Identification Test
4. Infant characteristics measured using the 20-item Bates Infant Characteristic Questionnaire (6-month version)

Completion date
02/11/2009

Eligibility

Key inclusion criteria
1. Couples expecting their first baby
2. No current serious medical or psychiatric complications
3. Both the parents of the expected baby sufficiently involved in the pregnancy to agree to participate
4. Sufficient competence in English to benefit from the therapeutic intervention and complete questionnaires
5. Couples must be over the age of 18 years old
6. Must be attending maternity services at one of the recruitment centres

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
120

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/05/2007

Date of final enrolment
01/12/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Free Hospital
Pond Street

London
United Kingdom
NW3 2QG

Study participating centre
University College Hospital
25 Grafton Way
London
United Kingdom
WC1E 6DB

Sponsor information

Organisation
The Tavistock and Portman NHS Foundation Trust

ROR
https://ror.org/04fx4cs28

Funder(s)

Funder type
Charity

Funder Name
Mental Health Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as consent was not obtained from participants to use the data for analyses other than evaluation of the efficacy of the intervention.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

Results article	21/09/2021	22/09/2021	Yes	No