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Targeted social care for highly vulnerable pregnant women: protocol of the Mothers of Rotterdam cohort study

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ABSTRACT

Introduction Social vulnerability is known to be related to ill health. When a pregnant woman is socially vulnerable, the ill health does not only affect herself, but also the health and development of her (unborn) child. To optimise care for highly vulnerable pregnant women, in Rotterdam, a holistic programme was developed in close collaboration between the university hospital, the local government and a non-profit organisation. This programme aims to organise social and medical care from pregnancy until the second birthday of the child, while targeting adult and child issues simultaneously. In 2014, a pilot in the municipality of Rotterdam demonstrated the significance of this holistic approach for highly vulnerable pregnant women. In the 'Mothers of Rotterdam' study, we aim to prospectively evaluate the effectiveness of the holistic approach, referred to as targeted social care.

Methods and analysis The Mothers of Rotterdam study is a pragmatic prospective cohort study planning to include 1200 highly vulnerable pregnant women for the comparison between targeted social care and care as usual. Effectiveness will be compared on the following outcomes: (1) child development (does the child show adaptive development at year 1?) and (2) maternal mental health (is maternal distress reduced at the end of the social care programme?). Propensity scores will be used to correct for baseline differences between both social care programmes.

Ethics and dissemination The prospective cohort study was approved by the Erasmus Medical Centre Ethics Committee (ref. no. MEC-2016–012) and the first results of the study are expected to be available in the second half of 2019 through publication in peer-reviewed international journals.

Trial registration number NTR6271; Pre-results.

Strengths and limitations of this study

- Societal valorisation of knowledge through valuable collaboration between academics, government and a non-profit organisation to support the healthy development of future generations.
- The ecologically valid study design allows for results directly generalisable to the actual population, but increases risks of true effects being masked by unmeasured confounders.
- Comparison of two types of social care on multiple domains (maternal-specific and child-specific outcomes), collected through a multimethod approach: questionnaires, developmental and cognitive tasks and video and photo observations in the home environment.
- Unique insights into a notoriously difficult-to-reach population of highly vulnerable pregnant women, their problems and potential care pathways for these problems.
- The findings of our study are likely to be generalisable to other contexts and countries, since vulnerable pregnant women are present in all countries and improvement of care for these women may contribute to better outcome measures.

INTRODUCTION

There is an abundance of evidence that low socioeconomic status (SES) is related to decreased (mental) health of the individual.[1–3] Exposure to determinants such as low income, unemployment, being a single parent and living in a deprived neighbourhood increases levels of chronic stress, which in turn results in a decreased health status of the individual.[1 4] Also, persons who chronically experience stress might be left with diminishing overall resources to adequately cope with stressful situations, which often results in a downward spiral of more unhealthy and unfavourable behaviour.[1 2 4–9] Moreover, these negative effects do not only affect the individual, but also the persons who are closely related to them and even the next generation.[3 10–16] Decreased self-sufficiency and increased levels of chronic stress may negatively influence competent parenting and a healthy parent–child relationship.[17 18] Also, prenatal exposure to stress can have detrimental effects on the (unborn) child: including, but not limited to, being born small for gestational age, developing obesity and behavioural problems in early childhood and later in life.[10–16 19–29]

In general, care for people with problems related to low SES is the responsibility of the social care system. In the Netherlands, social

care is usually carried out by a community social care team: a multidisciplinary team of professionals located in the neighbourhood of their clients.[30] Based on the needs of the client, care is either focused on adult issues (such as financial problems or unemployment) or problems regarding children and adolescents (such as underperformance and skipping school). This strict separation of the social care in adult and child care seems logical, but is in most cases not optimal, since impact of risk and adversity is not limited to one generation and can simultaneously affect both parent(s) and child(ren).

Within Rotterdam, 57% of the children grow up in a neighbourhood with low SES, and within the Netherlands, it has the highest percentage of children growing up in poverty (25%), in a family living on welfare (19%), with a low parental level of education (20%) and with one or both parents being unemployed (10%).[31–36] Moreover, in the period of 2009–2014, perinatal mortality and morbidity within the municipality of Rotterdam (8.9 and 173.4 per 1000 deliveries, respectively) was higher than the national promillage (7.8 and 141.7 per 1000 deliveries respectively).[36–40] Within the municipality of Rotterdam, the Erasmus Medical Centre, the local government and a non-profit organisation are combining their expertise to support the healthy development of future generations. By improving the psychosocial situation of highly vulnerable pregnant women, these stakeholders aim to support a healthy development of the (unborn) child. Recently, a holistic approach was developed to integrate medical and social care for highly vulnerable pregnant women and their (unborn) children, as well as targeting adult and child issues simultaneously.[41] A pilot study of this holistic approach (n=281 pregnant women) in 2014 highlighted the magnitude of the problem within Rotterdam, as well as the accumulation of problems experienced by these women (see table 1). The programme was considered promising to optimise care for these highly vulnerable women, but yet awaits empirical testing of its effectiveness.

With the 'Mothers of Rotterdam' (MoR) study, we will prospectively evaluate the effectiveness of this targeted social care on two domains: (1) child development; and (2) maternal mental health.

Table 1 Descriptive characteristics of pilot period for Targeted Social Care (TSC), based on self-report (n=281)

	Categories	Amount
Age Missing (9.6 %)	Adolescent 15–19 years	19 (7.5%)
	Young adult 20–25 years	84 (33.1%)
	Adult 26–30 years	72 (28.3%)
	Adult 31–35 years	50 (19.7%)
	Adult 36–40 years	19 (7.5%)
	Adult > 40 years	10 (3.9%)
Parity	Nullipara	77 (29.4%)
	Primipara	91 (34.7%)
	Multipara (2–6 children)	94 (35.9%)
Sufficient income Missing (47.7%)	Sufficient income	24 (16.3%)
	Partly sufficient income	46 (31.3%)
	Insufficient income	77 (52.4)
Debt Missing (24.2%)	Yes	171 (80.3%)
	No	42 (19.7%)
Living conditions Missing (16.4%)	Independent housing	142 (60.4%)
	Institution	10 (4.3%)
	No personal residence	75 (26.7%)
	Homeless	5 (2.1%)
	Other	3 (1.3%)
Imminent eviction Missing (30.6%)	Yes	33 (16.9%)
	No	161 (82.6%)
	Not applicable	1 (0.5%)
Educational level Missing (50.9%)	No/only primary education	12 (8.8%)
	Secondary general education	34 (24.6%)
	Vocational education	86 (62.3%)
	College, university	6 (4.3%)
Deprived neighbourhood Missing (12.5%)	Yes	164 (66.7%)
	No	82 (33.3%)

METHODS

The MoR study consists of a pragmatic prospective cohort designed to evaluate the effectiveness of targeted social care (TSC) for highly vulnerable pregnant women in Rotterdam. TSC is a selective prevention programme aimed at improving developmental opportunities for children from highly vulnerable pregnant women. TSC will be compared with care as usual for this high-risk population.

Targeted social care

The TSC programme has been developed in close collaboration between the university hospital, the local government and a non-profit organisation, and is carried out by one of the social care providers within the municipality of Rotterdam. TSC has been developed to exclusively suit the population of highly vulnerable pregnant women and their (unborn) children. The programme emphasises social care in the home environment and also encourages compliance to medical care. The programme promotes a healthy lifestyle, as well as regular visits to appropriate healthcare providers: general practitioner, midwife, gynaecologist or other medical specialists and preventive child healthcare physicians. By doing so, the programme aims to reduce avoidance of care and to promote preventive health behaviour.

The programme consists of three specific stages: (1) reducing acute stress by taking over pressing actions from the mother; (2) creating a calm and more structured environment, in collaboration with the mother, to enable the development of a secure mother–child relationship and ensuring a healthy infant development; and (3) enhancing parenting skills and sensitivity of the mother, while also stimulating the mother's autonomy and encouraging her to actively participate in society.

The care is provided by a team of social care professionals and social work students (University of Applied Sciences, final year of their bachelor's degree). Quality of care is ensured by close supervision of the professionals with regard to the progress of the student, the mother and the social care programme. Improvement in the situation of the mother is evaluated in detail every 3 months, and care is handed over to the professional at any time, when necessary. The intensity of TSC is high at the start (two home visits a week during the first stage) and decreases over time until the second birthday of the child (one home visit every 2 weeks during the final stage).

Care as usual

The social care provided by the community social care team is characterised by a distinction between adult issues (such as financial problems or unemployment) and problems regarding children and adolescents (such as underperformance and skipping school). The care providers are trained in detecting (potential) problems while providing basic support and guidance for solving or reducing these problems. If necessary, the client is referred to other (social) care and welfare organisations for additional support. Care is of average intensity, with approximately one visit every (two) week(s), over a period between 3 and 9 months.

Eligibility criteria and allocation

Eligible participants are all pregnant women, residing in Rotterdam, who are classified as potentially highly vulnerable by their referring party. The referring party is most often an obstetric professional, but also social workers, the highly vulnerable pregnant woman herself or her social network, can refer to the programme. Women are categorised as potentially highly vulnerable when at least three are indicated within the following domains: pregnancy, residence, finance, occupation, parenting, health, social functioning and safety (see online supplementary appendix 1).

After referral, a home visit is planned to assess the number and intensity of the problems within the household. When a pregnant woman is indeed identified as highly vulnerable during the home visit (criteria summarised in table 2), she is allocated to either TSC or care as usual. For several postal codes care as usual is not available for this particular population. As a result, women are assigned to care as usual when it is available in their residential neighbourhood, and to TSC when it is not (see online supplementary appendix 2). Due to the pragmatic character of the study, blinding is not possible. However, risk of bias is reduced since both participants and care providers are unaware of the actions of the other social care programme. Furthermore, data will be processed by researchers blinded to the social care programme the mother was allocated to.

Although both programmes are allowed to collaborate with other (social) welfare organisations and professionals, participants are not allowed to be involved in both TSC and care as usual. Both social care programmes are voluntary and discontinued at the request of the mother.

Participant timeline

Pregnant women are informed about the study during the first home visit. Informed consent is obtained from the pregnant women, as well as for their (unborn) children. When fathers have acknowledged the child to be their own, informed consent from the father is required as well. To also include as many non-Dutch speaking participants as possible, all study materials are also available in English, Arabic, Polish, Turkish and Spanish.

Women who do not provide written consent or who are not proficient in one of the available languages are not able to participate in the study, while both social care programmes remain available to them. If a woman stops with the social care programme, participation in the study

Table 2 Eligibility, inclusion and exclusion criteria

Eligibility criteria	Inclusion criteria	Exclusion criteria*
► Women residing in the municipality of Rotterdam ► Women who are pregnant during informed consent procedure ► Women who are identified as highly vulnerable by referring party: at least three problems (from a total of 46 problems) divided over at least two different problem domains (eight in total).†	► Women who are identified as highly vulnerable during home visit: at least three problems (from a total of 46 problems) divided over at least two different problem domains (eight in total).† ► Women who agreed to receive care from either TSC or care as usual.	► Women who did not provide written consent. ► Women who were not sufficiently skilled at understanding either: – Dutch – English – Arabic – Polish – Spanish – Turkish

*Teenage mothers and women with previous pregnancies are not excluded from the study.
†For a complete overview of the problems and the problem domains, see online supplementary appendix 1.

will be continued with permission of the woman until her child is 2 years old. When a woman stops her participation in the study, social care will be continued until no longer deemed necessary.

Data will be prospectively collected at a maximum of nine different time points: (1) at inclusion; (2) 6 weeks after the start of social care, but before delivery; (3) 6 weeks postpartum; (4) 6 months postpartum; (5) 12 months postpartum; (6) 18 months postpartum; (7) 24 months postpartum; (8) at the end of social care; (9) and 6 months after ending social care. Time point *1* will not be available for all women, since it is possible that they have delivered their baby before meeting the criterion of receiving 6 weeks of social care. When the participant discontinues the social care programme prematurely, measurements from the last two time points are collected (8 and 9), and the research will continue regarding mother and child outcomes. Reasons for discontinuation are registered by their care provider. As acknowledgement for their contribution, and to encourage continuation in the study, participants are rewarded with a voucher worth €10, for participation at each time point.

To collect data on the well-being of the mother and her child, a multimethod approach is used to gather data: questionnaires, developmental and cognitive tasks and video and photo observations in the home environment. Data on medical and social care use are collected from the registries from social care professional(s); general practitioner(s); obstetric professional(s); the Preventive Child Health Centre, the Vaccination Office; and the Child Abuse/Domestic Violence Agency. For a complete overview of the measurement points and measurement types, see online supplementary appendix 3.

Outcomes

Primary outcomes of the study are child development and maternal mental health. Additionally, the process outcome of the study is received social care.

Child development

The proportion of children with a delay in overall development was measured at 1 year of age with the Ages and Stages Questionnaire (ASQ).[42 43] The ASQ will be completed by the mother and measures development in the following domains: communication, gross motor skills, fine motor skills, problem solving abilities and social interaction.[42 43] Delay is defined as below clinical cut-off for at least one of these domains.[42 43]

Maternal mental health

A reduction of stress, anxiety and/or depression within at least one category was measured with the Depression, Anxiety and Stress Scales.[44 45] The difference between the scores at the start and at the end of social care will be used for primary analyses.[46]

Process evaluation

Self-sufficiency of the mother, as reported by her social care provider on the Self-Sufficiency Matrix (SSM),[47] is used to evaluate the received social care programmes. The SSM is filled out by the social care provider at the start of the programme, every 6 months for the duration of either social care programme, at the end of the social care programme and after the 6-month follow-up period.

Sample size calculation

Sample size calculations were performed in G-power[48] using a power of 80% and a type I error of 0.05. We hypothesise that TSC will have more favourable results on both primary outcomes.

To test an expected difference between 12.5% of children with a developmental delay in the TSC programme and 20% of children within care as usual, a total of 752 are needed (376 children per programme). For maternal mental health, 385 mothers per programme (770 in total) are needed to demonstrate a difference between 50% of mothers with improvement in TSC and 40% of mothers with improvement in care as usual. To account for dropout of participants, we aim to include 1200 highly vulnerable pregnant women within the study.

Statistical methods

Given the pragmatic design of this study, we will use analytical methods appropriate for quasi-experimental study designs, often used in evaluations of policy changes, which closely resembles our situation. Consequently, the analysis will only be performed per protocol. Also, since randomisation was not possible, propensity score matching will be used to correct for potential confounding due to allocation bias. The matched endpoints will be analysed using multivariable regression models. In these models, we will include potentially confounding determinants collected during the study, and outcomes from other domains.

Subgroup analyses will be performed, stratified by: ethnicity, parity, marital status, age of the mother and cognitive ability. These subgroup analyses will only be performed when large enough numbers are available (at least 20 observations in the smallest group). In case of missing data on potential confounders in the questionnaires, multiple imputation will be used, using Multivariate Imputation by Chained Equations (MICE) procedures and 10 imputed data sets.[49] For the (photo and video) observations, imputation of missing variables will not be performed and missing data from the registries will be considered as 'not present'.

Ethics and dissemination

The study was approved in January 2016 (ref. no. MEC-2016–012) and deemed compliant to the Dutch law on Medical Research on Humans. The study was registered in the Dutch Trial Registry (NTR6271). All data will be registered and analysed anonymously. Source documents and data will be preserved and stored for 15 years after study completion. The first results of the study are expected to be available in the second half of 2019 through publication in peer-reviewed international journals.

Declaration of interest

Investigators confirm that there are no conflicts of interest for the overall trial.

Trial status

The MoR study started on 4 January 2016 and will be recruiting participants until 31 December 2019. The end date for data collection is 31 December 2020.

Roles and responsibilities of coordinating centre

The coordinating centre (Erasmus MC) will ensure adherence to Good Clinical Practice Guidelines in collecting, storing, and processing of data anonymously.

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Contributors EAPS and JPG conceived the study. JPG, LCMB, MH and MWG initiated the study design. RK, PP, LCMB, AB and EAPS provided methodological expertise in the trial design. JPG is grant holder. MH and MWG implemented the trial design and will conduct primary statistical analyses and report results. All authors contributed to refinement of the study protocol and approved the final manuscript.

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Disclaimer The funder had no role in the design of this study, and will not have any role during its execution, analyses, interpretation of data or decision to submit results.

Competing interests None declared.

Patient consent Detail has been removed from this case description/these case descriptions to ensure anonymity. The editors and reviewers have seen the detailed information available and are satisfied that the information backs up the case the authors are making.

Ethics approval Research Ethics Committee of the Erasmus Medical Centre.

Provenance and peer review Not commissioned; externally peer reviewed.

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