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The feasibility phase of a community antenatal lifestyle programme [The Lifestyle Course (TLC)] for women with a body mass index (BMI) ≥ 30 kg/m²



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ABSTRACT

Introduction: maternal obesity [body mass index (BMI) ≥ 30 kg/m²] is a cause for concern because of increasing rates and risk of associated complications. However, little is known about how to improve the health of women with a BMI ≥ 30 kg/m².

Objective and methods: a 10-week antenatal lifestyle programme (The Lifestyle Course – TLC), underpinned by behaviour change theory, was developed in a programme of research which included a prospective, multicentred, feasibility phase ($n=227$). Participants had a BMI ≥ 30 kg/m² at the start of their pregnancy, planned to deliver in two areas of Greater Manchester and were aged 18 or over. The objectives were to (1) assess the feasibility of the intervention and (2) to pilot the trial processes and outcome measures.

Findings: (1) *Trial intervention:* only 22% of women in the feasibility phase had received gestational weight advice prior to the study. One or more TLC sessions were attended by 79% of women and 97% said they would recommend TLC to a friend due to the content suitability, perceived personal gains and extra care received. Changes to the TLC were suggested and implemented in the pilot phase. (2) *Trial processes:* recruitment rates (36%), retention rates (100%) and questionnaire completion rates up to one year (33%) were found. Daily general 'lifestyle' diaries and pedometers were not acceptable data collection tools (response rates of 32% and 16% respectively). However, specific food diaries were acceptable (response rates of 80–81%). The major challenge was the collection of maternal weight data at the follow-up points. **Conclusions and implications:** the antenatal intervention (TLC) designed for this programme of work appears to suit the needs of women with a BMI ≥ 30 kg/m². The need for an antenatal intervention is clear from this study and also highlights reflections on effective communication with pregnant women with a BMI ≥ 30 kg/m². Lessons learnt for designing a future trial include effective ways to communicate with pregnant women with a BMI ≥ 30 kg/m².

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Introduction

Pregnancy is a time of transition, both physically and emotionally, providing health professionals with an opportunity to intervene to encourage behaviour change (National Institute for Health and Clinical Excellence [NICE], 2007; Phelan, 2010). Antenatal interventions have the potential for short- and long-term change for mother, baby and family. As a result, early interventions for public health issues such as obesity [a body mass index (BMI) ≥ 30 kg/m², according to World Health Organization] (WHO, 1999) are high priority for Governments around the world (e.g., NICE, 2010; Allan, 2011).

Global data suggests that the number of women registering for antenatal care with a BMI ≥ 30 kg/m² is growing (e.g., Centre for Disease Control & Prevention, 2007). For example, in England, a study of 34 maternity units found that the percentage of pregnant women who have a BMI ≥ 30 kg/m² in the first trimester of their pregnancy increased from 7.6% to 15.6% over a 19-year period (Heslehurst et al., 2010). Maternal obesity is widely accepted as increasing risk for maternal complications (Denison et al., 2008) and fetal complications (Cedergren and Kallen, 2005) that can ultimately result in longer hospital in-patient stays and an increased cumulative health service cost (e.g., Sebire et al., 2001; Chu et al., 2008; Denison et al., 2009). In the long term, an association between maternal obesity and childhood obesity is also evident (e.g., Pirkola et al., 2010). Thus, the possible issues associated with maternal obesity need to be addressed in pregnancy by discussing lifestyle behaviours, in particular, women who start their pregnancy with a BMI ≥ 30 kg/m² should be targeted (Centre for Maternal and Child Enquiries [CMACE] and Royal College of Obstetricians and Gynaecologists [RCOG], 2010; NICE, 2010).

A recent meta-synthesis examining the maternity experience for women with a BMI ≥ 30 kg/m² offered support for lifestyle advice (Smith and Lavender, 2011). Pregnancy was an ideal time for intervention as women were aware of the benefits of a healthy lifestyle and were more accepting of weight gain than prior to their pregnancy (Smith and Lavender, 2011). Several qualitative studies conducted in the UK and Australia have found that women are not currently receiving this lifestyle advice (Schmied et al., 2010; Furness et al., 2011; Olander et al., 2011; Davis et al., 2012). Not receiving weight management advice and support can lead to increased anxiety (Brown and Avery, 2012). A lack of clear maternal obesity objectives was highlighted in a qualitative study of community-based service providers as the reason for a lack of available maternal obesity services (Smith et al., 2011). There are few antenatal or postnatal weight management or lifestyle interventions that have been designed and evaluated for use with women with a BMI ≥ 30 kg/m² in England resulting in little evidence on the optimum intervention for use with this target group (Campbell et al., 2009; Messina et al., 2009). Two large longitudinal antenatal randomised controlled trials (RCTs) have recently started in the UK with results due in a few years time: The UK Pregnancies Better Eating and Activities Trial (UPBEAT) study (ISRCTN: 89971375) and The Healthy Eating and Lifestyle in Pregnancy (HELP) study (ISRCTN: 25260464). Recent literature reviews have suggested that, for overweight and obese pregnant women, antenatal interventions that include dietary and lifestyle components are associated with reduced gestational weight gain and lower incidence of gestational diabetes (Oteng-Ntim et al., 2012), increased postnatal weight maintenance (Tanentsapf et al., 2011) and better outcomes for mother and baby (Thangaratnam et al., 2012). However, it is warned that these conclusions are based upon low-medium quality research and it is suggested that more longitudinal data is needed (Oteng-Ntim et al., 2012).

The current article will present data from a programme of work to design and evaluate an innovative community-based 10-week

antenatal lifestyle course (The Lifestyle Course – TLC) for women with a BMI ≥ 30 kg/m². The intervention designed for this study differs from the currently running studies such as HELP or UPBEAT interventions as it is run in the community setting as favoured by this target group (Atkinson and Edmunds, 2009), is underpinned by behaviour change theory (as suggested by NICE, 2010), provided a group-based exercise session (Renjilian et al., 2001) and had midwifery presence throughout. Following the Medical Research Council (MRC) complex intervention framework (MRC, 2009), a feasibility phase was conducted to inform the development of a suitable and acceptable intervention for the target population. This data informed a pilot RCT. This aims to ensure that the study design and processes are robust and able to answer the research questions, in particular to assess the utility of the selected outcome measures and help specify the most suitable primary outcome measure. No efficacy hypothesis was tested at this stage due to the feasibility nature of the work. This study will add to the evidence-base of using group-based lifestyle programmes to prevent obesity in the UK (as suggested as required by the Department of Health, 2009) and will inform a future formally powered RCT to test the efficacy of the TLC intervention with an appropriate target population. This article has two main objectives using data from the feasibility phase to (1) assess the feasibility of the intervention and (2) to pilot the trial process. The outcome measures of the pilot RCT have been reviewed following collection of the one-year postnatal data (December 2012–June 2013) and will be presented at a later date along with discussion of a potential future RCT.

Methods

Sample and procedure

A prospective, multicentred, feasibility study was conducted from July 2009 to May 2012. Ethical approval was gained from the local NHS Research Ethics Committee (Ref: 09/H1003/80), local NHS Research and Development Departments and the University of Manchester. Recruitment took place in two areas of Greater Manchester (Bolton and Oldham) which are defined by the Association of Public Health Observatories and Department of Health, (2011), as more deprived. They were selected for their high levels of poor health outcomes which includes obesity rates. Women were recruited at antenatal clinics through three routes with all eligible women being approached; research midwives employed as part of the research team approached eligible women, eligible women were referred to the research midwives by other health professionals and research midwives displayed posters around the antenatal clinics with a contact number and email for women to self-refer to the study. Women were eligible if they were planning to have their baby in the two areas, were aged 18 or over, had a booking BMI ≥ 30 kg/m² and would be between 13 and 28 weeks gestation. The suitability of each woman to take part in antenatal physical activity was assessed by the research midwife with the woman's obstetrician being consulted in complex cases. Taken into consideration for referral were the woman's obstetric and/or medical history, for example, pregnant women who had a very raised BMI (≥ 50 kg/m²) or a history of vaginal bleeding would necessitate consultant obstetric approval.

All women in the feasibility phase were invited to attend TLC and take part in the study. The number of women recruited but who did not want to attend the intervention was small so this group is not included in this paper. Twenty women were recruited to each 10 week course with the expectation of attending each week. The sessions were not run as a drop in as it was not a rolling programme. In both cases, mixed-methods data was collected

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