

BMJ Open Which factors play a role in the decision of mothers to participate in child follow-up examinations after participation in an RCT?: a semi-quantitative study

Tamara den Harink ^{1,2}, Annemieke Hoek ³, Henk Groen ⁴,
Tessa J Roseboom^{1,2}, Arend van Deutekom⁵

To cite: den Harink T, Hoek A, Groen H, *et al*. Which factors play a role in the decision of mothers to participate in child follow-up examinations after participation in an RCT?: a semi-quantitative study. *BMJ Open* 2022;**12**:e057694. doi:10.1136/bmjopen-2021-057694

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-057694>).

Received 25 September 2021
Accepted 19 July 2022



© Author(s) (or their employer(s)) 2022. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

Correspondence to

Dr Tamara den Harink;
t.denharink@amsterdamc.nl

ABSTRACT

Objectives To determine which factors contribute to the decision of mothers to participate with their child in follow-up (FU) examinations after participation in a randomised controlled trial (RCT) prior to conception.

Design A cross-sectional survey, including Likert-scale items. Comparisons will be made between respondents who participated in all FU rounds of data collection and those who did not participate in any FU round with their child.

Participants Women who participated in an RCT investigating the effect of a preconception lifestyle intervention (LIFestyle study: Netherlands Trial Register: NTR1530) were invited to participate with their child in three FU data collections when the child had a mean age of 4.2 years, 4.6 years and 6.5 years, respectively. FU rounds included a health questionnaire, physical examination and cardiac assessment, successively.

Results Sixty-seven respondents were included, of whom 7 (10%) did not participate in any FU round and 24 (36%) participated in all FU rounds. Women who participated with their child in all 3 FU data collection rounds felt more involved in the FU research (95.8%) and agreed more often that the FU was introduced well (91.7%) as compared with women that did not participate in any FU data collection round with their child (14.3% and 28.6%, respectively). Participants of FU rounds more often agreed that participation felt like a health check for their child as compared with non-participants. In addition, participants of the physical examination and cardiac assessment more often let their decision to participate depend fully on their child, as compared with non-participants (39.4% vs 17.7% and 52.5% vs 24%, respectively).

Conclusions To increase participation rates in future FU studies of children after maternal participation in an RCT, we suggest to involve women in the design of the FU study, to emphasise possible perceived benefits of participation and to encourage women to actively involve their child in the decision of participation.

INTRODUCTION

Maternal health before and during pregnancy is associated with health outcomes in children throughout the life course.^{1 2} Observational studies have shown that maternal health

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ We designed a questionnaire to determine which factors influence the decision of mothers to participate with their child in follow-up (FU) examinations after participation in a randomised controlled trial prior to conception.
- ⇒ The questionnaire was piloted among randomly picked women to ensure all possible factors were addressed in the questionnaire.
- ⇒ We compared respondents who participated in all three FU rounds of data collection to those who did not participate in any FU round with their child.
- ⇒ All respondents answered the questionnaire at one moment in time and after completion of the FU, thus a change in opinion during FU was not accounted for.

conditions before or during pregnancy, such as obesity and diabetes, are associated with an increased incidence of obesity, type 2 diabetes and hypertension in their children.³⁻⁵ Interventions before or during pregnancy could potentially affect children's health in the long run. In order to assess causal effects of such interventions on children's health, long-term follow-up (FU) of randomised controlled trials (RCTs) evaluating interventions before or during pregnancy is needed.

Currently, only 16% of RCTs evaluating effects of interventions during pregnancy include an FU to evaluate the effect of the intervention on the child's health.⁶ This low number may be due to the high costs and long timespan that exceeds most funding schemes, as well as logistical and legal challenges.⁷ An important challenge which hampers the unique ability of trials to assess causality is that such long-term FU studies in children of mothers who participated in RCTs investigating effects of interventions before or during pregnancy often face high loss-to-FU. Loss-to-FU can induce selection

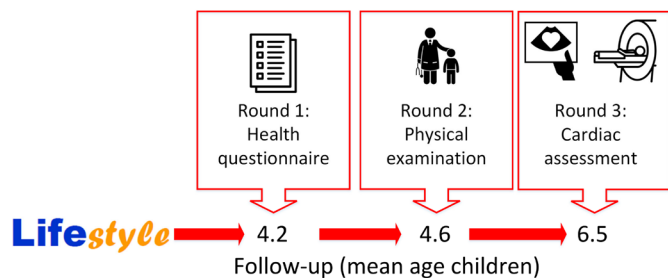


Figure 1 FU data collection rounds. FU, Follow-up.

bias, leading to imbalances in study groups, which can jeopardise the ability to assess causality.^{8,9} Importantly, the validity of the study results correlate directly with the degree of loss-to-FU.¹⁰

The importance of the preconception period in determining the long-term health in children has been well established and recognised by several important authorities, including the WHO and the International Federation of Gynaecology and Obstetrics.^{21–19} Studies aimed at improving preconception health in women with obesity are conducted more often and should be seen as a public health priority.^{11,20–22} With the alarming rise of maternal obesity worldwide, the effect of preventive strategies on the detrimental effects of maternal obesity on long-term health in children is necessary, and high follow-up rates must be ensured.^{14,23} To minimise loss-to-FU in this type of FU, an understanding of factors that influence the decision for participation is important. For this semi-qualitative study, we included women who participated in an RCT investigating the effects of a lifestyle intervention before pregnancy on fertility outcomes in women with obesity. During the FU, which was introduced after inclusion for the RCT, children born to these women were invited to participate in several FU data collection rounds to investigate their long-term health.²⁴ The FU rounds in the children included a questionnaire addressing the child's health, a physical examination near their homes and a cardiac assessment in a hospital. We aimed to determine which factors play a role for mothers when deciding whether or not to participate with their child in FU research. Eventually, our results could be implemented in the

design of future FU studies of children after maternal participation in an RCT, and eventually limit loss-to-FU.

METHODS

Participants

We included women who participated in the LIFEstyle study, an RCT investigating a preconception lifestyle intervention.²⁵ The intervention study included infertile women with obesity and these women were randomly assigned to a lifestyle intervention before fertility care or prompt fertility care.²⁵ Women were eligible if they conceived a healthy child within 24 months after randomisation in the LIFEstyle study, had given permission to be contacted for FU research of their child and had given available contact information.²⁵ The FU study was set up to evaluate the long-term health in both women who participated in the RCT and their children.²⁴ In this study, we focused solely on the FU of the children. The FU in the children consisted of three consecutive rounds of data collection in a period of 8 years after randomisation (see figure 1). Table 1 demonstrates an overview of the mean age and FU rates of the children during the different FU rounds. In summary, during the first FU round, the children had a mean age of 4.2 years and mothers were asked to fill in a health questionnaire addressing the child's general health and behaviour as well as monitoring the child's food intake 3 times in 1 week. In addition, an accelerometer was provided to measure the physical activity of the children. The second round, the physical examination, consisted of a one-time visit to a mobile research vehicle near the family's home when the children had mean age of 4.6 years. We measured anthropometry, body composition, cardiometabolic health and behavioural components.²⁶ During the physical examination, participants were asked to give consent for an additional buccal swab, faeces sample and/or blood sample to gain more insight in the biochemical and genetic profiles. The third FU round was a cardiac assessment in a hospital when the children in the study had a mean age of 6.5 years. This cardiac assessment consisted of an echocardiogram and a cardiac MRI study. Participation during this round took

Table 1 Overview of the FU data collection rounds

	Health questionnaire	Physical examination	Cardiac assessment
Eligible, n	305	156	242
Participated, n	107	48	60
FU rate, %	35.1	30.8	24.7
Intervention group, n(%)	43 (40.1)	17 (33.3)	24 (40.0)
Age of the children, years*	4.2 (0.8)	4.6 (1.0)	6.5 (1.1)
*Data are presented as mean (SD) FU, follow-up			

approximately 1 hour for the echocardiogram and an additional 1 hour for the cardiac MRI.

FU participation questionnaire

We used the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cross-sectional reporting.²⁷ All eligible participants were asked to complete a questionnaire with statements regarding participation in FU research of their child (see online supplemental figure 1) and provide written consent. The participation questionnaire consisted of two parts. The first part addressed topics including (1) experience during the original intervention study, (2) communication to participants, (3) knowledge and stigma of the subject of research and (4) understanding of the importance of the research topic. The second part consisted of statements specific for the FU round and were asked separately for each FU round to determine which factors played a role in participation for each round. These statements included: (1) I let the decision of participation depend fully on my child, (2) my child was too young to participate, (3) participation would feel like a health check for my child, (4) the distance to the research location would be too far, (5) the research visit would be too burdensome for my child and (6) the research visit would take too much time.

In total, the questionnaire included 70 statements and mothers had to indicate how much they agreed on a 5-point Likert scale: 1 stated 'strongly disagree', 2 stated 'disagree', 3 stated 'neutral', 4 stated 'agree' and 5 stated 'strongly agree'. Apart from the Likert scale, we used multiple choice and open questions.

Patient and public involvement

Participants were involved in the conduct of this research. During the feasibility stage, we pretested the questionnaire among 10 participants to optimise coverage of questions and assure clarity of the questions. Based on their feedback, we added two questions to the questionnaire: 'If the follow-up study would have been introduced by someone from the original study team, I would have been more likely to participate' and 'The link between the original intervention study and the follow-up study was clear' (online supplemental figure 1).

Data analysis

For the analysis, we combined 4 (agree) and 5 (strongly agree) to summarise the percentage of agreement. To assess which factors contributed to the decision to participate in the study, we compared the answers of respondents that participated in all three FU rounds with respondents that did not participate in any FU round with their child. In addition, we compared the level of agreement between participants and non-participants within each FU round to determine if there were certain factors associated with participation for a specific type of FU. Comparisons between groups were made using Fisher's exact test. The

analyses were performed using IBM SPSS V.26. A p value of <0.05 was considered statistically significant.

Sensitivity analysis

To assess possible selection bias, we compared our group of participants with all eligible non-participants.

RESULTS

In total, 341 children were conceived within 24 months after randomisation and 211 dyads were eligible and approached (see figure 2). Sixty-seven respondents (31.8%) completed the FU participation questionnaire. For an overview of the respondents and their previous participation in FU with their child, see figure 3. Table 2 demonstrates the baseline characteristics of the respondents who completed the questionnaire. See online supplemental table 2 for the STROBE checklist.

Table 3 demonstrates the incidence of agreement between respondents who participated in all FU rounds with their child (n=24) and those who did not participate in any FU round (n=7). The vast majority of both groups wanted to contribute to knowledge regarding both obesity and fertility (table 3). Women who participated with their child during all FU rounds felt more involved in the FU as compared with those women who did not participate in any FU round (95.8% vs 14.3%, respectively, $p<0.001$). In addition, women who participated with their child in all FU rounds agreed that the way the FU study was introduced was good as compared with women who did not previously participate (91.7% vs 28.6% respectively, $p=0.002$). Respondents who did not participate in any child FU data collection round would have appreciated it if the plan for the FU would have been clearer at the start of the RCT and agreed more often that they would have been more likely to participate if someone familiar from the RCT would have introduced the FU, as compared with women who participated in all FU rounds (table 3). In addition, respondents who did not participate in any child FU round agreed more often that the subject of the research has to be something they personally find interesting. Almost all respondents who participated in all FU rounds agreed that the importance of the FU was clear (95.8%) as compared with 42.9% of the respondents who did not participate in any child FU round.

FU round specific questions

Table 4 demonstrates the agreement between participants and non-participants per FU round. Overall, women who participated with their child during any FU round agreed more often that participation felt like a health check for their child as compared with non-participants. This difference increased in subsequent FU rounds, ranging from 55.1% and 38.9% between participants and non-participants in the health questionnaire to 68.3% and 28% in the cardiac assessment, respectively.

In the health questionnaire, participants and non-participants did not differ significantly on statements,

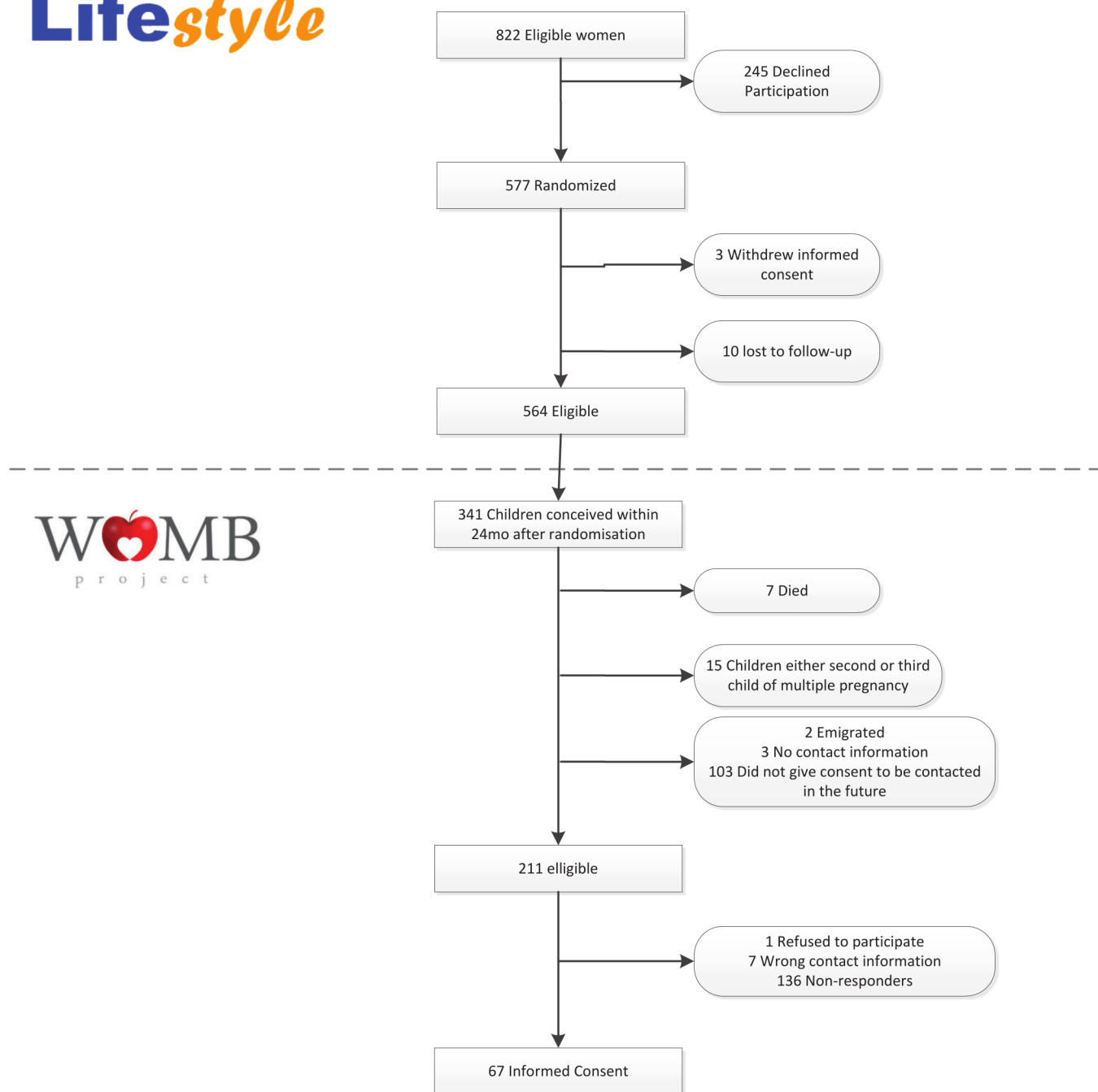


Figure 2 Participation flowchart.

including if the questionnaire took too much time (16.3% vs 11.2%, respectively), if the questionnaire was too burdensome for their child (4.2% vs 11.2%) or if they believed that their child was too young to participate (20.4% vs 11.1%). Participants and non-participants of the physical examination or cardiac assessment round did differ on these statements. Respondents who participated in these FU rounds let the decision of participation more often fully depend on their child (39.4% for the physical examination and 52.5% for the cardiac assessment) as compared with non-participants (17.7% for the physical examination and 24% for the cardiac assessment).

Non-participants of the physical examination or cardiac assessment agreed more often that the research visit was too burdensome for their child (24.2% vs 3% for the physical examination and 37.5% vs 0% for the cardiac assessment) and took too much time (17.7% vs 3.1% for the physical examination and 25% vs 2.4% for the cardiac assessment) and they felt like their child was too young to participate as compared with participants (38.3% vs 6.1% for the physical examination and 52% vs 2.4% for the cardiac assessment) (table 4).

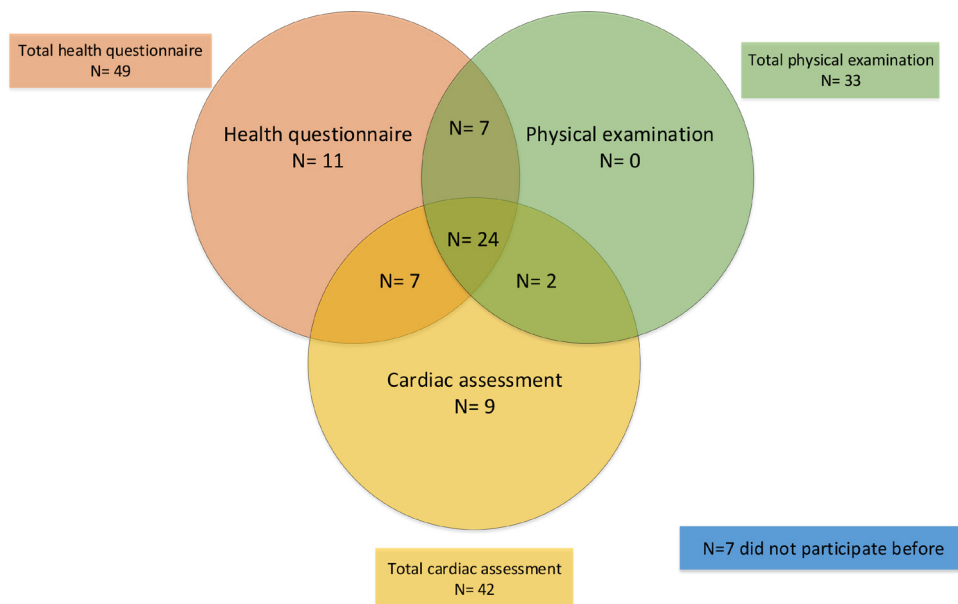


Figure 3 Distribution of respondents and previous FU participation with their child. FU, follow-up.

Sensitivity analysis

Online supplemental table 1 demonstrates the differences between respondents that participated in our study and all eligible non-respondents. Respondents of our study were older as compared with non-respondents (30.1 years (SD: 3.9 years) vs 28.8 years (SD: 4.6 years), respectively, $p=0.05$) and their children had a higher birth weight (3506.2 g (SD: 655.5 g) vs 3325.5 g (SD: 568.8 g), respectively, $p=0.04$).

DISCUSSION

We sought to determine which factors contribute to the decision of mothers to participate with their child in FU examinations after participation in an RCT prior to conception. We found that all women who had been invited for FU of their child wanted to contribute to knowledge of the research topic. Women who participated in all rounds of data collection with their child felt more involved in the study compared with those who did

not participate. In addition, women who participated with their child in the physical examination or cardiac assessment more often perceived participation as a health check for their child and let their child decide to participate as compared with those who did not participate. This suggests that important reasons for participating in FU research are feeling involved, perceiving the FU as a health check for their child and actively involving their child in the decision to participate.

In pregnant women anticipating to participate in a birth cohort study, altruism and health-related motivations are important factors for participation in research.^{28 29} In our study, both participants and non-participants wanted to contribute to knowledge of the research topic. In addition, half of the respondents that participated in all FU rounds with their child agreed that it is important that the research topic is something that they find personally interesting, implying altruism might not be the only driving factor for participation in FU research of their child. Perceiving the FU as a health check for their child seemed to positively influence the decision for participation. This is in line with previous research, demonstrating that participation in longitudinal research was not mainly driven by altruism as expected beforehand, but by the perceived benefits during the FU visit, such as the medical care.³⁰ Barnett *et al* assessed maternal experience of participation in FU research with children after participation in a longitudinal cohort study during pregnancy.³¹ They identified health improvements in children as a significant motivator for mothers to remain in the study after their child was born.³¹ In addition, Garg *et al* identified perceived health benefits, regular monitoring of their child and a gain in health-related knowledge as important incentives for mothers when participating in research with their children.²⁹ Patients seeking fertility care considered the safety of the assisted reproductive

Table 2 Baseline characteristics

N=67	
Mean age mothers, years	39.0 (4.1)
Education mother, %	
Primary education	1 (1.6)
Secondary education	13 (20.3)
Intermediate vocational education	37 (57.8)
Higher vocational education and university	13 (20.3)
Mean age of the child, years	7.5 (0.8)
Intervention group, %	24 (35.8)
Female (child), %	30 (44.8)
Data are presented as mean (SD), or n (%).	

Table 3 Agreement between respondents who participated in all FU rounds and respondents who did not participate in any FU round

Statement	Participated in all FU rounds (n=24)		Did not participate in any FU round (n=7)		P value
	n	%	n	%	
The importance of the intervention study was clear	22	91.7	5	71.4	0.21
I want to contribute to knowledge regarding obesity	22	91.7	5	71.4	0.21
I want to contribute to knowledge regarding fertility	24	100	6	85.7	0.23
I felt that during the original trial there was enough attention for my wish to conceive	21	87.5	5	71.4	0.56
I felt involved in the intervention study	18	75	3	42.9	0.17
I felt involved in the FU	23	95.8	1	14.3	<0.001
The way in which the intervention study was introduced by the health professional was good	21	87.5	5	71.4	0.56
The way in which the FU was introduced by the health professional was good	22	91.7	2	28.6	0.002
The link between the intervention study and the FU was clear	17	70.8	2	28.6	0.08
I would have liked it if it was clear at introduction of the intervention study, that there would be an FU	3	12.5	6	85.7	0.001
If the FU would have been introduced by someone from the RCT, I would have been more likely to participate	0	0	4	57.1	0.001
There was too much time in between the several visits of the FU	3	12.5	2	28.6	0.56
I would have wanted to receive more updates during the FU	7	29.2	2	28.6	1.0
I think it's important that the subject of research is something that I find personally interesting	11	45.8	7	100	0.03
I knew that obesity and fertility were related	19	79.2	7	100	0.56
I knew that cardiovascular diseases are more common in females	14	58.3	5	71.4	0.68
I knew that the later health of a child may depend on lifestyle during pregnancy	16	66.7	6	85.7	0.64
The importance of the FU was clear	23	95.8	3	42.9	0.005
I thought that there was a negative stigma regarding obesity during the introduction of the intervention study	7	29.2	2	28.6	1.0
I think it's important to receive an incentive after participation	10	41.7	3	42.9	1.0

FU, follow-up; RCT, randomised controlled trial.

technique, which includes long-term outcomes in their unborn children, the most important research topic.³² Therefore, we believe it is important to emphasise perceived healthcare benefits to women participating in FU research for their child.

In our study, respondents who participated in all FU rounds felt more involved as compared with non-participants. Previous research exploring reasons for participation in longitudinal health studies demonstrated that a sense of loyalty and membership is positively associated with participation.³⁰ Studies that involved patients in the study design process have higher participation rates,³³ and the findings are more readily translated into clinical practice.³⁴ Non-participants would have been more inclined to participate if the FU would have been introduced at inclusion of the RCT, and if the health outcomes assessed in FU would be relevant to them. This is in line with

studies assessing the impact of patient and public involvement on enrolment and retention studies. These studies found that patient involvement in setting up studies, for example, in the direction and priorities of studies, leads to more active and involved participants.^{35–37} This might also lead to a clearer understanding of the importance of the FU, something we found to be two times as high among participants as compared with non-participants. Therefore, we believe that patient involvement in priority setting, designing and execution of research will lead to a higher participation rate and facilitate implementation of knowledge gained by research into practice.³⁸

Women who participated with their child in the FU consisting of physical examination or cardiac assessment more often allowed their child to decide if she/he wanted to participate. Thus, when inviting women with their children for FU research, it is important to encourage women

Table 4 Agreement between participants and non-participants per FU round

Statement	Health questionnaire			Physical examination			Cardiac assessment		
	P (%)	NP (%)	P value	P (%)	NP (%)	P value	P (%)	NP (%)	P value
I let the decision of participation depend fully on my child	14.2	22.2	0.47	39.4	17.7	0.06	52.5	24	0.04
My child was too young to participate	20.4	11.1	0.49	6.1	38.3	0.003	2.4	52	<0.001
Participation would feel like a health check for my child	55.1	38.9	0.28	63.6	38.2	0.05	68.3	28	0.003
The distance to the research location would be too far	4.1	5.6	1.0	0	26.5	0.002	29.3	48	0.12
The research visit would be too burdensome for my child	4.2	11.2	0.29	3	24.2	0.03	0	37.5	<0.001
The research visit would take too much time	16.3	11.2	0.72	3.1	17.7	0.11	2.4	25	0.009

FU, follow-up; NP, non-participant; p, participant.

to actively involve their child in the decision of participation, and to ensure appropriate information for the child, such as a separate invitation letter. A review on the participation of children in research identified that only 15% of research claiming to involve children in the design of studies actually involved them in the decision to participate in research,³⁹ even though involving children in all aspects of research leads to more committed and involved participants.⁴⁰ When designing an FU of RCTs before or during pregnancy, representative children should be involved to ensure that the research appeals to children.

The FU rates in the data collection rounds were low. The FU rate of the physical examination was significantly lower than the same protocol that was carried out by the same team during the FU of an RCT of assisted reproduction techniques in couples with unexplained or mild male subfertility (The INeS study) (33% vs 57%, respectively).⁴¹ Importantly, although both FU studies were carried out in the same way, in the same time period, and by the same team, the participation rates differed. Both studies investigated infertile couples aiming to conceive, but the current study only included women who also were overweight and obese, while the INeS trial did not. Moreover, the lifestyle intervention was aimed at weight loss rather than conception, while the INeS study randomised women to different fertility treatments. Although the link between obesity and subfertility was known to most participants in our study, women included in our RCT did not seek medical care for their weight even though the intervention offered to these women consisted of lifestyle counselling. We hypothesise that offering a lifestyle intervention for an unfulfilled wish to become pregnant might have led to a feeling of disconnect between their medical problem and the treatment offered. These factors could have played a role in the reduced willingness to participate in our FU.

Respondents filling out our questionnaire reported not feeling they were being stigmatised due to their

weight. However, this may have been different for non-responding women. Previous research has demonstrated that women with obesity are often faced with weight stigma.^{42–43} Raising the topic of weight by healthcare providers requires a sensitive and respectful approach, using neutral terminology (eg, ‘weight’ and ‘body mass index’ instead of ‘obese’) and preferably asking women about their language preferences.⁴⁴ Moreover, healthcare providers should not make assumptions about diet, activity levels, motivations and perceived difficulties.⁴⁵ Women with obesity contemplating a pregnancy are often not aware of the detrimental consequences of maternal obesity on their future child.^{46–49} However, once they are made aware of these consequences they are often willing to improve their health and postpone their wish to conceive in order to make lifestyle changes.⁵⁰ Unfortunately, if information about lifestyle is provided by a healthcare professional, it is often unclear and inconsistent, which makes women perceive the message as unimportant.⁵¹ Taken together, healthcare providers working with women with obesity contemplating a pregnancy need to be adequately informed regarding the benefits of a healthy lifestyle during pregnancy and educated to address this topic in a non-judgmental manner.^{45–46} In addition, the social context has a great influence on lifestyle and should be recognised when implementing a lifestyle intervention in women with obesity.⁵² Furthermore, if the social context is included, women feel supported in daily life and perceive the implementation of a healthy lifestyle during pregnancy as a shared responsibility instead of an individual responsibility.⁵¹

There are limitations to our study. First, only 32% of all eligible mothers and children participated in this study, making our results prone to selection bias. If we compare women who participated in our study with eligible non-respondents, we find that respondents were older and gave birth to children with a higher birth weight (online supplemental table 1). This participation bias is often

reported in FU of birth cohorts.^{53 54} However, the differences were small and several extreme low birthweight children in the non-respondent group were responsible for the significant difference in birth weight (data not shown). We found no other differences between respondents and eligible non-respondents. Therefore, we believe our results are representative of the entire group of participants and the findings are likely to reflect true reasons to participate in FU of children after maternal participation in an RCT. Second, our study includes women with obesity and infertility, which may limit the generalisability of our results. Women with obesity contemplating a pregnancy are not often in contact with healthcare providers, unless they experience problems to conceive.⁵⁵ As a result, trials assessing a preconception lifestyle intervention in women with obesity often include women that present with fertility issues.⁵⁵ However, we expect the motivation to participate in a study that stimulates a healthy lifestyle to optimise child's health is independent of a women's fertility status. Therefore, we believe that our findings also apply to other women.

CONCLUSION

When designing an FU in children after maternal participation in an RCT of an intervention before or during pregnancy, loss-to-FU might be limited by emphasising the possible perceived benefits of participation, such as a health check for their child, and to encourage women to actively involve the child in the decision of participation. In addition, it is important to actively involve women and representative children in the design of the FU study to stimulate the sense of involvement and increase understanding of the importance of the FU, which seems to increase participation rates. Implementing these factors could prevent loss-to-FU and eventually help to assess causality between early life and later health.

Author affiliations

¹Department of Epidemiology and Data Science, Amsterdam UMC, Locatie AMC, Amsterdam, The Netherlands

²Amsterdam Reproduction and Development research institute, Amsterdam, The Netherlands

³Department of Obstetrics and Gynaecology, University Medical Centre Groningen, Groningen, The Netherlands

⁴Department of Epidemiology, Rijksuniversiteit Groningen, Groningen, The Netherlands

⁵Division of Pediatric Cardiology, Department of Pediatrics, Erasmus MC-Sophia Children's Hospital, Rotterdam, The Netherlands

Twitter Henk Groen @Groen62H

Acknowledgements We would like to thank Casey Johnson for his assistance reviewing this manuscript for grammar.

Contributors TdH and AvD designed the research protocol. TdH was responsible for safely storing all data, extracting and analysing the data and writing the article. AH, HG and TJR all carefully reviewed the article. AH, HG, TJR and AvD were involved in the set-up of the original intervention study and follow-up study. All authors provided intellectual input and were involved in the writing of the article. TdH, AvD and TJR acted as guarantors.

Funding This work was supported by a grant of the Dutch Heart Foundation (grant number: 2013T085) and a Postdoc Stipend of Amsterdam Reproduction and

Development. The initial LIFeStyle trial was supported by a grant from ZonMW, the Dutch Organization for Health Research and Development (grant number: 120620027).

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval The Medical Ethics Committee of the UMC Groningen deemed that the Medical Research Involving Human Subjects Act (WMO) did not apply to this study (METc 2019/221) and official approval was not required. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Data are available on reasonable request. Please contact authors for information on data availability.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iDs

Tamara den Harink <http://orcid.org/0000-0001-7365-0619>

Annemieke Hoek <http://orcid.org/0000-0003-4441-7142>

Henk Groen <http://orcid.org/0000-0002-6629-318X>

REFERENCES

- Barker DJ, Gluckman PD, Godfrey KM, *et al*. Fetal nutrition and cardiovascular disease in adult life. *Lancet* 1993;341:938–41.
- Stephenson J, Heslehurst N, Hall J, *et al*. Before the beginning: nutrition and lifestyle in the preconception period and its importance for future health. *The Lancet* 2018;391:1830–41.
- Godfrey KM, Reynolds RM, Prescott SL, *et al*. Influence of maternal obesity on the long-term health of offspring. *Lancet Diabetes Endocrinol* 2017;5:53–64.
- Reynolds RM, Allan KM, Raja EA, *et al*. Maternal obesity during pregnancy and premature mortality from cardiovascular event in adult offspring: follow-up of 1 323 275 person years. *BMJ* 2013;347:f4539.
- Liu L, Ma Y, Wang N, *et al*. Maternal body mass index and risk of neonatal adverse outcomes in China: a systematic review and meta-analysis. *BMC Pregnancy Childbirth* 2019;19:105.
- Teune MJ, van Wassenaer AG, Malin GL, *et al*. Long-term child follow-up after large obstetric randomised controlled trials for the evaluation of perinatal interventions: a systematic review of the literature. *BJOG* 2013;120:15–22.
- Olmedo-Requena R, Amezcua-Prieto C, Al Wattar BH, *et al*. Variations in long-term outcome reporting among offspring followed up after lifestyle interventions in pregnancy: a systematic review. *J Perinat Med* 2020;48:89–95.
- Dumville JC, Torgerson DJ, Hewitt CE. Reporting attrition in randomised controlled trials. *BMJ* 2006;332:969–71.
- Aggarwal R, Ranganathan P. Study designs: Part 4 - Interventional studies. *Perspect Clin Res* 2019;10:137–9.
- von Allmen RS, Weiss S, Tevaearai HT, *et al*. Completeness of follow-up determines validity of study findings: results of a prospective repeated measures cohort study. *PLoS One* 2015;10:e0140817.
- Poston L, Caleyachetty R, Cnattingius S, *et al*. Preconceptional and maternal obesity: epidemiology and health consequences. *Lancet Diabetes Endocrinol* 2016;4:1025–36.

- 12 Chen C, Xu X, Yan Y. Estimated global overweight and obesity burden in pregnant women based on panel data model. *PLoS One* 2018;13:e0202183.
- 13 Fleming TP, Watkins AJ, Velazquez MA, *et al.* Origins of lifetime health around the time of conception: causes and consequences. *Lancet* 2018;391:1842–52.
- 14 Barker M, Dombrowski SU, Colbourn T, *et al.* Intervention strategies to improve nutrition and health behaviours before conception. *Lancet* 2018;391:1853–64.
- 15 The L. Campaigning for preconception health. *Lancet* 2018;391:1749–391.
- 16 Hanson MA, Bardsley A, De-Regil LM, *et al.* The International Federation of Gynecology and Obstetrics (FIGO) recommendations on adolescent, preconception, and maternal nutrition: "Think Nutrition First". *Int J Gynaecol Obstet* 2015;131 Suppl 4:S213–53.
- 17 Jacob CM, Baird J, Barker M, *et al.* The importance of a life-course approach to health: chronic disease risk from preconception through adolescence and adulthood: white paper 2017.
- 18 Who, Who. Diet, nutrition and the prevention of chronic diseases - Introduction. DIET, NUTRITION AND THE PREVENTION OF CHRONIC DISEASES. 9162003:1–149.
- 19 Organization WH. Promoting optimal fetal development: report of a technical consultation 2006.
- 20 Legro RS, Hansen KR, Diamond MP, *et al.* Effects of preconception lifestyle intervention in infertile women with obesity: the FIT-PLESE randomized controlled trial. *PLoS Med* 2022;19:e1003883.
- 21 Rouissi M, Jean-Denis F, Belan M, *et al.* A preconception lifestyle intervention improves some gestational outcomes and neonatal markers of adiposity in women with obesity and infertility. *Fertility and Sterility* 2020;114:e466–7.
- 22 LeBlanc ES, Boisvert C, Catlin C, *et al.* Prepare randomized clinical trial: acceptability, engagement, and lifestyle effects of a weight loss intervention beginning in pre-pregnancy. *Obes Sci Pract* 2022;66.
- 23 World health organisation (WHO). Obesity and overweight, fact sheet, 2021. Available: <https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight>
- 24 van de Beek C, Hoek A, Painter RC, *et al.* Women, their offspring and improving lifestyle for better cardiovascular health of both (womb project): a protocol of the follow-up of a multicentre randomised controlled trial. *BMJ Open* 2018;8:e016579.
- 25 Mutsaerts MAQ, van Oers AM, Groen H, *et al.* Randomized trial of a lifestyle program in obese infertile women. *N Engl J Med* 2016;374:1942–53.
- 26 Menting MD, van de Beek C, Rono K, *et al.* Effects of maternal lifestyle interventions on child neurobehavioral development: follow-up of randomized controlled trials. *Scand J Psychol* 2019;60:548–58.
- 27 von Elm E, Altman DG, Egger M, *et al.* The strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *Lancet* 2007;370:1453–7.
- 28 Soule MC, Beale EE, Suarez L, *et al.* Understanding motivations to participate in an observational research study: why do patients enroll? *Soc Work Health Care* 2016;55:231–46.
- 29 Garg N, Round TP, Daker-White G, *et al.* Attitudes to participating in a birth cohort study, views from a multiethnic population: a qualitative study using focus groups. *Health Expect* 2017;20:146–58.
- 30 Mein G, Seale C, Rice H, *et al.* Altruism and participation in longitudinal health research? insights from the Whitehall II study. *Soc Sci Med* 2012;75:2345–52.
- 31 Barnett W, Brittain K, Sorsdahl K, *et al.* Maternal participant experience in a South African birth cohort study enrolling healthy pregnant women and their infants. *Philos Ethics Humanit Med* 2016;11:3.
- 32 García D, Brazal S, Lindenberg F, *et al.* Identification of research priorities in infertility and assisted reproduction: an international, multicentre study. *Reprod Biomed Online* 2020;40:238–44.
- 33 Abshire M, Dinglas VD, Cajita MIA, *et al.* Participant retention practices in longitudinal clinical research studies with high retention rates. *BMC Med Res Methodol* 2017;17:30.
- 34 Dean CR, Bierma H, Clarke R, *et al.* A patient-clinician James Lind alliance partnership to identify research priorities for hyperemesis gravidarum. *BMJ Open* 2021;11:e041254.
- 35 Forsythe LP, Carman KL, Szydlowski V, *et al.* Patient engagement in research: early findings from the patient-centered outcomes research Institute. *Health Aff* 2019;38:359–67.
- 36 Townsend R, Duffy JMN, Khalil A. Increasing value and reducing research waste in obstetrics: towards woman-centered research. *Ultrasound Obstet Gynecol* 2020;55:151–6.
- 37 Crocker JC, Ricci-Cabello I, Parker A, *et al.* Impact of patient and public involvement on enrolment and retention in clinical trials: systematic review and meta-analysis. *BMJ* 2018;363:k4738.
- 38 Skovlund PC, Nielsen BK, Thaysen HV, *et al.* The impact of patient involvement in research: a case study of the planning, conduct and dissemination of a clinical, controlled trial. *Res Involv Engagem* 2020;6:43.
- 39 Jacquez F, Vaughn LM, Wagner E. Youth as partners, participants or passive recipients: a review of children and adolescents in community-based participatory research (CBPR). *Am J Community Psychol* 2013;51:176–89.
- 40 Vaughn LM, Wagner E, Jacquez F. A review of community-based participatory research in child health. *MCN Am J Matern Child Nurs* 2013;38:48–53.
- 41 Mintjens S, Menting MD, Gemke RJB, *et al.* The effects of intrauterine insemination and single embryo transfer or modified natural cycle in vitro fertilization on offspring's health-Follow-up of a randomized clinical trial. *Eur J Obstet Gynecol Reprod Biol* 2019;242:131–8.
- 42 Puhl RM, Heuer CA. Obesity stigma: important considerations for public health. *Am J Public Health* 2010;100:1019–28.
- 43 Duarte C, Matos M, Stubbs RJ, *et al.* The impact of shame, Self-Criticism and social RANK on eating behaviours in overweight and obese women participating in a weight management programme. *PLoS One* 2017;12:e0167571.
- 44 Auckburally S, Davies E, Logue J. The use of effective language and communication in the management of obesity: the challenge for healthcare professionals. *Curr Obes Rep* 2021;10:274–81.
- 45 Flannery C, McHugh S, Anaba AE, *et al.* Enablers and barriers to physical activity in overweight and obese pregnant women: an analysis informed by the theoretical domains framework and COM-B model. *BMC Pregnancy Childbirth* 2018;18:178.
- 46 Furness PJ, McSeveryn K, Arden MA, *et al.* Maternal obesity support services: a qualitative study of the perspectives of women and midwives. *BMC Pregnancy Childbirth* 2011;11:69.
- 47 Shub A, Huning EY-S, Campbell KJ, *et al.* Pregnant women's knowledge of weight, weight gain, complications of obesity and weight management strategies in pregnancy. *BMC Res Notes* 2013;6:278.
- 48 Cha E, Smart MJ, Braxter BJ, *et al.* Preconception care to reduce the risks of overweight and obesity in women of reproductive age: an integrative review. *Int J Environ Res Public Health* 2021;18. doi:10.3390/ijerph18094582. [Epub ahead of print: 26 04 2021].
- 49 Kandel P, Lim S, Pirota S, *et al.* Enablers and barriers to women's lifestyle behavior change during the preconception period: a systematic review. *Obes Rev* 2021;22:e13235.
- 50 Brackenridge L, Finer N, Batterham RL, *et al.* Pre-pregnancy weight loss in women with obesity requesting removal of their intra-uterine contraceptive device in order to conceive: a pilot study of full meal replacement. *Clin Obes* 2018;8:244–9.
- 51 Vanstone M, Kandasamy S, Giacomini M, *et al.* Pregnant women's perceptions of gestational weight gain: a systematic review and meta-synthesis of qualitative research. *Matern Child Nutr* 2017;13. doi:10.1111/mcn.12374. [Epub ahead of print: 21 11 2016].
- 52 Dencker A, Premberg Åsa, Olander EK, *et al.* Adopting a healthy lifestyle when pregnant and obese - an interview study three years after childbirth. *BMC Pregnancy Childbirth* 2016;16:201.
- 53 Park B, Choi EJ, Ha E, *et al.* A study on the factors affecting the follow-up participation in birth cohorts. *Environ Health Toxicol* 2016;31:e2016023.
- 54 Daniels JL, Savitz DA, Bradley C, *et al.* Attitudes toward participation in a pregnancy and child cohort study. *Paediatr Perinat Epidemiol* 2006;20:260–6.
- 55 Lan L, Harrison CL, Misso M, *et al.* Systematic review and meta-analysis of the impact of preconception lifestyle interventions on fertility, obstetric, fetal, anthropometric and metabolic outcomes in men and women. *Hum Reprod* 2017;32:1925–40.