Supplement material

1. Research Information Letter [1]

SHAPES

About the SHAPES research

A pregnant woman's Body Mass Index (also known as BMI) is used to identify which women might need extra care in pregnancy. Currently, women with a high BMI get extra care. However, BMI might not be the best measure to use and women's body shape in early pregnancy might be better. SHAPES will explore if other measurements, such as waist size or ultrasound scans, can be used to identify which women would benefit most from extra care during pregnancy. We need 1400 women with a whole range of BMIs to take part.

A member of the clinical team at NuTH might discuss this research with you over the phone if they call to book your routine 12-week scan appointment, or in the waiting room when attending for your scan appointment. If you are interested in taking part in this research, you will receive more detailed written information about the study to read and discuss with the research team. All the extra body shape measurements will be done at your 12-weeks scan appointment, which will take about an extra 45 minutes. As a thank you for your time, you will receive 3 photos of your baby from your 12-week scan, and you can be entered into a prize draw to win £100 shopping vouchers.

We only have a limited number of research appointments available each week, so unfortunately, we can't offer them to everyone. This means you may not be contacted about the research. If you think you might be interested in taking part, you can contact us directly. If you do not want anyone to approach you about this research, please let us know and we won't contact you.

Contact details: email: nuth.rhnresearch@nhs.net phone: 0191 2820362

For more information about this study, please visit our website: http://research.ncl.ac.uk/shapes/

Yours sincerely

Victoria Murtha, Principal Investigator for the SHAPES Study, Royal Victoria Infirmary, Newcastle upon Tyne Hospitals NHS Foundation Trust

[1] This letter goes out to women alongside a generic letter from NUTH about research in maternity services, alongside summaries of other research projects active at the same time as SHAPES.

2. Participant Information Sheet (PIS)

Study of **h**ow **a**diposity in **p**regnancy has an **e**ffect on outcome**s:** the SHAPES study

Participant Information Sheet

Research Centre: The Newcastle Upon Tyne Hospitals NHS Foundation Trust

Chief Investigator: Nicola Heslehurst, Newcastle University

Principal Investigator: Victoria Murtha, Newcastle upon Tyne NHS Foundation Trust, Reproductive Health Research Team, The Royal Victoria Infirmary (RVI), 0191 2820362, nuth.rhnresearch@nhs.net

We would like to invite you to take part in a research study. Before you decide if you want to take part it is important that you understand what it will involve. Please take time to read this document and discuss it with others if you wish. You will have the opportunity to discuss the research with a member of the team when you attend for your 12-week scan appointment and we encourage you to do this if there is anything you are unsure of. If you have received this information sheet before your scan appointment, you can contact us directly if you would like to discuss anything in advance.

Part one of this document tells you about the purpose of the study and what would happen if you decided to take part. Part two provides information about optional extras, which are extra parts of this research that you can choose whether or not you want to take part in. Part three gives more details about the conduct of the research. Further contact details are on the last page of this document.

Part One

What is the purpose of the research? This research will explore body shape in early pregnancy and how it impacts on the health of women and babies. The NHS uses Body Mass Index (BMI) to identify who might need extra care in pregnancy. However, there may be more accurate measures than BMI to understand who would most benefit from extra pregnancy care. We will look at body shape in early pregnancy, and need women with a whole range of BMIs to take part. This research will inform how maternity services provide care to improve health of women and babies.

Why have I been invited? The study is being carried out at the RVI. We are inviting pregnant women attending this hospital for a 12-week scan, and aim to include 1400 women in this study.

What will happen to me if I take part? A member of the research team will discuss the research with you at your 12-week scan appointment. If you decide to take part, you will be asked to sign a consent form. We will take some extra body shape measurements on the same day as your scan

[Type here]

appointment. The sonographer who is doing your 12-week scan will take some extra ultrasound measurements. A female researcher will then take all the extra measurements in a private room. These will include your waist size, hip size, upper arm size, neck size, skinfold measurements of fat stored underneath the skin, height and weight. We will need to draw some lines on your arms, stomach and back using an erasable pen. It would be helpful if you could wear a loose-fitting top and lightweight clothing on the day. Most of the measurements will be taken using a tape measure. The skinfold measurements will use callipers to compress the skin, but this should not cause any pain. You will also be asked to fill in a short questionnaire to get some extra information about you, for example your age, ethnic group and postcode. We will review your routine maternity notes after you have had your baby so that we can get information about your pregnancy, for example, how you delivered your baby. You don't need to do anything else for this research after your 12-week scan appointment.

Will I learn more about my own body shape measurements or health? No. We don't yet know which body shape measurements are most accurate, so we can't give you any feedback on this.

What will happen to the results of the research study? The results from this study will be used to see how well body shape measurements relate to health during pregnancy. This will give us a better idea of which women and babies would benefit the most from extra care during pregnancy. The results will be published in a scientific journal so that other researchers and health professionals can learn from this research. You would not be identified in any results we present or publish. If you would like to receive a summary of results from the study, then we can share these with you.

What are the possible benefits and disadvantages of taking part? Your hospital ultrasound scan appointment will take up to 45 minutes longer than normal. There are no direct benefits for you during this pregnancy but taking part in this research could help to improve care of for women and their babies during pregnancy in the future. To say thank you for taking part you will receive a photograph mount with three printed pictures of your baby from your 12-week scan which will be given to you on the day of your scan appointment. You can also take part in a research prize draw which will be drawn at the end of the research. There are 40 prizes of £100 shopping vouchers to be won.

Do I have to take part? No. Participation is voluntary, and it is up to you to decide if you want to participate in the study. If you do not want to take part, you do not have to give a reason and your care will not be affected in any way. If you have received this document before your scan appointment and you decide that you don't want to take part in the study, you can either contact us to let us know before attending for your appointment or turn up and let us know on the day. Your scan appointment will go ahead as planned whether you decide to take part in this research or not.

What if I change my mind? You are free to withdraw from the study at any time, without giving a reason. If you change your mind, your care will not be affected in any way. If you want to withdraw from the study, please use the contact details on page 1 of this document.

Part Two: Optional Extras[2]

There are two optional extras for this research. You can still take part in the research without agreeing to either of these optional extras, or you can choose to agree to one or both of them.

SHAPES Study Interviews: You will be asked by the research team if you are happy to share your contact details with the research team at Newcastle University for a second study related to SHAPES. The second study involves being interviewed about your experiences of having the extra body shape measurements taken. If you agree to share your contact details now, this does not mean that you are agreeing to be interviewed, you are only agreeing to share your contact details with the research team. Not all women who share their details will be contacted as there will be 1400 women in SHAPES and only around 30 women will be interviewed. If you are contacted about the interview study, you will receive detailed written information and have the opportunity to discuss with the researchers before deciding whether to take part. If you don't want to take part, you do not have to give a reason and your care won't be affected in any way.

Future research about long-term health and well-being of women and their children: We would like to explore whether body shape in early pregnancy is linked to the future health and well-being of women and their children. An example of the type of research question we would be asking would be "can waist size measured at 12-weeks in pregnancy identify which women or children develop diabetes later in life?" If pregnancy measurements are useful, then we could plan ways to support women and children after pregnancy to try and improve long-term health and well-being.

To do this future research, we would need your consent to store your NHS number, name and date of birth, and your baby's NHS number and date of birth, linked to your SHAPES Study ID number. This is needed so that we can link the SHAPES data with routinely collected health data in the future, through organisations such as NHS Digital, hospital attendance data and GP records. For example, we could link to medical records to see if you or your child has been diagnosed with diabetes at any point after pregnancy. This extra research will only involve accessing routine electronic data and not any further contact with you. Any researcher who wants to access your health records can only do so if you consent to the use of your data in this way, and will follow best ethical and legal practice.

Part Three

Will my taking part in the study be kept confidential? Yes. Newcastle upon Tyne Hospitals NHS Foundation Trust, based in the United Kingdom, is the sponsor for this study and will act as the data controller for it. This means they are responsible for looking after your information and using it properly. Newcastle upon Tyne Hospitals NHS Foundation Trust will keep identifiable information about you for 5 years after the study has finished. Newcastle upon Tyne Hospitals NHS Foundation Trust will collect information from you and/or your medical records for this research study in

[2] Women in the SHAPES study can choose to consent to any combination of the optional extras, or none of them, and can still take part in SHAPES

accordance with our instructions. Only trained clinical-research team members will have access to your information.

Your rights to access, change, or move your information is limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personal identifiable information possible.

Individuals from Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The research team will pass these details to individuals at NuTH along with the information collected from you and/or your medical records upon request for audit purposes. The only people in NuTH who will have access to information that identifies you will be people who need to contact you to discuss this study or audit the data collection process. People outside the NuTH will have no access to your identifiable information and will not be able to access your medical notes, find out your name, NHS number or contact details.

If you give consent to participate in the study, we would use non-identifiable personal information (through allocating a study ID number) to analyse the data and report the findings. Any paper documents will be stored in a locked fire-resistant cupboard at the RVI. To allow us to analyse the anonymised data it will be transferred to a secure server on the Newcastle University system and stored in accordance with the regulations of the Data Protection Act 2018 and the Newcastle upon Tyne Hospitals NHS Foundation Trust Caldicott guidelines. You can find out more about how we use your information at:

- www.hra.nhs.uk/information-about-patients/
- https://newcastlejro.com/research/new-study/data-security
- Email the NUTH Data Protection Officer, Richard Oliver, richard.oliver2@nhs.net

Future research: If you consent to us keeping your data for future research, it will be stored on a secure server at Newcastle University. Newcastle University will be the data controller for the future research. All data protection regulations will be followed. Even if you agree to us storing this data, we will still need to get ethical approval to access your data again for future research. This would be to make sure we are using the data in the way we have told you about in this document, and that you have consented to. If you consent to us storing your data, we will not share it with anyone else or use it for any other purpose than described in this document. If you consent to us storing this data for future research, you are free to withdraw at any time, without giving a reason. Any information already collected can be destroyed if you wish. If you change your mind, your care will not be affected in any

way. To withdraw from this future research, please contact the chief investigator (contact details on the last page of this document).

What will happen to information collected about me for the research study? The information we collect during the study will be analysed (or processed) to enable us to explore if body shape measurements in early pregnancy relate to the health of women and babies.

Who is organising and funding the research? This project is funded by the Department of Health via the National Institute for Health Research. It is being led by Dr Nicola Heslehurst who is a researcher at Newcastle University.

Who has reviewed the study? This study has been reviewed and given a favourable opinion by North East - Newcastle & North Tyneside 1 Research Ethics Sub-Committee. The study design has been reviewed by Sponsor (NuTH). Members of the public were involved in review of a scope (lay summary), design and incentives for this research.

Extra Contact Details

Where can I get further information about the study? If you have any questions or concerns about participating in the study please contact the clinical lead for this research at the RVI (Victoria Murtha, 0191 2820362, nuth.rhnresearch@nhs.net), or the Chief Investigator from Newcastle University (Nicola Heslehurst, 0191 2083823, nicola.heslehurst@ncl.ac.uk).

What if there is a problem? If you are not satisfied with any aspect of the way you have been approached or treated during the course of this study, you should first speak to the research team (please see contact details on page 1) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, the normal National Health Service complaints mechanisms are available to you: please ask to speak to the complaints manager for the Hospital.

If you have any concerns about how you are treated in relation to this research study, you can raise these with the Patient Advice and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202.

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department, Tel: 0191 2231382 or 0191 2231454, Email: nuth.patient.relations@nhs.net Address: Patient Relations Department, Newcastle upon Tyne Hospitals NHS Foundation Trust

Thank you for taking the time to read this participant information sheet.

3. Inform consent

Participant Identifica

CONSENT FORM (SHAPES Study)

Study of **h**ow **a**diposity in **p**regnancy has an **e**ffect on outcome**s**

Chief Investigator: Nicola Heslehurst

Please initial box

1. I confirm that I have read the information sheet dated 08/02/2022 (version 2.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during this study may be looked at by individuals from the Newcastle upon Tyne Hospitals NHS Foundation Trust or relevant regulatory bodies where relevant to my taking part in this research (for example, for the purpose of audit of this research project). I give permission for these individuals to have access to my records. ☐
4. I agree for my information, gathered for this study, to be stored on a secure database for analysis on a Newcastle University server anonymously. ☐
5. I agree to take part in the above study. ☐

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

Please tick the relevant box and provide contact details below if you would like to:

a) take part in the prize draw □
b) receive a summary of results for the SHAPES study □

e-mail:

Telephone number:

Address:

4. Data items

Data item	Source		
	Measured for research during the research visit	Routine data: electronic records	Routine data: from paper-based notes
Questionnaire at research visit			
Age at booking*	x		
Gravidity	x		
Parity*	x		
Ethnic group*	x		
Postcode (linked with Index of Multiple Deprivation)*	x		
Smoking status (in the past 12 months and current smoking)*	x		
Alcohol intake (before pregnancy and current intake)*	x		
Substance use (before pregnancy)	x		
History of bariatric surgery (date and type)	x		
Medical record review at research visit			
Gestational age at research visit		x	x
Blood pressure at booking (systolic and diastolic)*		x	x
Previous caesarean delivery		x	x
Previous macrosomia		x	x
Diabetes history		x	x
Family history of diabetes		x	x
Previous spontaneous preterm birth or mid trimester loss between 16+0 and 34+0 weeks gestation		x	x
Cervical trauma		x	x
Cervical length < 25 mm		x	x
Family history of preeclampsia		x	x
Essential hypertension		x	x
Previous pregnancy hypertension		x	x
Chronic renal disease		x	x
Autoimmune disease		x	x
Last pregnancy >10 years ago		x	x
Previous low birth weight <10%		x	x
Previous still birth		x	x
Previous neonatal death within 4 weeks of life		x	x
Ultrasound and anthropometry measurements at research visit			
Subcutaneous fat	x		
Visceral fat	x		
Pre-peritoneal VAT	x		
Pre-peritoneal SAT	x		
Height at research visit	x		
Weight at research visit	x		
Waist circumference	x		
Hip circumference	x		
Neck circumference	x		
Mid upper arm circumference	x		
Skinfold thicknesses (subscapular, triceps, biceps, iliac crest, supraspinale)	x		
Follow up data linkage			
Congenital anomaly		x	
Reason for outcome data not being available		x	

Data item	Source		
	Measured for research during the research visit	**Routine data: electronic records**	**Routine data: from paper-based notes**
Number of antenatal scans (in antenatal clinic and fetal medicine)		x	
2nd trimester fetal growth (gestation at scan; fetal head circumference; abdominal circumference; femur length; estimated fetal weight)		x	
3rd Trimester fetal growth (gestation at scan; abdominal circumference; femur length; estimated fetal weight; umbilical artery PI; end diastolic flow; deepest pool)		x	
Hospital admissions in antenatal period		x	
Number antenatal clinic appointments (antenatal clinic, fetal medicine and maternity assessment unit)		x	
Infant date of birth or end of pregnancy		x	
Baby sex		x	
Viability (Live birth, still birth, late miscarriage 12-24 weeks)		x	
Neonatal death within 28 days of delivery (and date)		x	
Baby exam colour		x	
Apgar scores at 1 and 5 minutes		x	
Respiratory distress/resuscitation		x	
Feeding method (first feed and at discharge)		x	
Gestation at delivery		x	
Birthweight and percentile		x	
Induction of labour (and reason)		x	
Caesarean delivery (elective or emergency and reason)		x	
Instrumental delivery (and type)		x	
Place of delivery		x	
Water birth		x	
Maternal death (and date)		x	
Maternal folic acid supplementation		x	
Gestational diabetes diagnosis (and gestational age)			
Oral glucose tolerance test (OGTT test (fasting and 2 hour blood glucose)		x	
Preeclampsia (PE) diagnosis (and gestation)		x	
Pregnancy induced hypertension (PIH) diagnosis (and gestation); if yes (stillbirth, proteinuria, birthweight <3%, Abnormal umbilical artery Doppler waveform analysis, Renal insufficiency, Liver involvement, Haematological complications, Neurological complications)		x	
Manual removal of placenta		x	
Maternal infection during pregnancy		x	
Total blood loss 3rd stage and immediate postpartum		x	
Maternal length of stay in hospital		x	
Admission to neonatal intensive, high-dependency, special or transitional care (and length of stay)		x	
Antenatal and discharge medications (and description)		x	

* *A-priori* socio-demographic and clinical candidate predictor variables

Note: the full data dictionaory for SHAPES is available on request