**Additional File 1 - SPIRIT Checklist**

**Administrative Information**

**Title Item No 1** Using a peanut ball during labour versus not using a peanut ball during labour for

women using an epidural: study protocol for a randomised controlled pilot study

**Trial registration Item No 2a** Australian New Zealand Clinical Trials Registry, ACTRN insert number here

**No 2b** All items completed from the World Health Organization Trial Registration Data Set

**Protocol version Item No 3** Version 3 21st March

**Funding Item No 4** Partnership grant to be submitted to Western Sydney University and Nepean Blue Mountains Local Health District

**Roles and responsibilities Item No 5a** Associate Professor Virginia Skinner, Western Sydney University

Principle activities include education initially about the use of the peanut ball for midwives in the

birthing suite of Lithgow and Katoomba hospitals and overseeing the entire project. This includes

ensuring appropriate allocation of women to either intervention or control groups, data collection,

confidentiality of data and statistical analysis of final results.

Associate Professor Kenny Lawson, Translational Health Research Institute

Dr Lawson will be responsible for the conduct cost effectiveness analysis, producing preliminary

results from the pilot, making the business case for a larger trial, and undertaking a comprehensive

cost effectiveness analysis from the full trial. He will also lead on publications concerning the

economic and co-author relevant manuscripts.

Dr David Campbell, Nepean and Blue Mountains Anzac Memorial hospital

Assisting with recruitment and final writing of publications.

Dr Biing Yin, Lithgow hospital

Recruitment and education at Lithgow and final writing of publications.

Dr Wafa Al Omari, Nepean and Blue Mountains Anzac Memorial hospital

Assistance with education and recruitment and final writing publications.

Dr Robin Burr, Nepean hospital

Dr Burr's involvement will include continual consultation and expertise from an obstetric perspective whilst the study is in progress.  Dr Burr will be a key author on publications. Dr Burr will be involved

in the future planning of the randomised control study at Nepean hospital to follow.

Justine Elliott, Nepean hospital

Justine will be involved in the education of the midwives in the use of the peanut ball at both the

Blue Mountains and Nepean hospitals.

Madeleine Simpson, Blue Mountains Anzac Memorial hospital

Madeleine will be responsible for providing midwifery expertise and knowledge on site during the

pilot study and assisting with data collection in liaison with the Principal Investigator.

Sarah Cachia, Blue Mountains Anzac Memorial hospital

Sarah will be directly responsible for education of the midwives at the Blue Mountains Anzac

memorial hospital in the use of the peanut ball and provide midwifery expertise and knowledge on

site during the pilot  study.

Heather Borradale, Private hospital, Queensland

Heather has presented a poster at a recent national conference detailing use of the peanut ball. She works in a hospital that uses the peanut ball for women labouring with epidurals.

Deborah Gaynor

Deborah will be directly responsible for education of the midwives at Lithgow hospital in the use of

the peanut ball and provide midwifery expertise and knowledge on site during the pilot study.

Heather Reilly

Heather has had substantial research experience performing literature reviews, data collection and analysis of data in her previous research roles supporting professorial positions.

**Item No 5b** N/A

**Item No 5c** N/A

**Item No 5d** N/A

**Introduction**

**Background and rationale Item No 6a**

This pilot study would be implemented at the Blue Mountains Anzac Memorial and Lithgow hospitals, on a group of low risk women, to assess whether there is sufficient evidence for justification for using the peanut ball in a larger randomised controlled study. There is a need to further investigate these outcomes in Australia as Australia’s practising midwives are a distinct profession compared with Obstetric Nurses in the United States, so the United States results cannot be generalized to Australia. The National Institute for Health and Care Excellence Guidelines (NICE, 2017)1 states that there is no evidence pertaining to using a birth ball during labour and this project addresses this gap. In fact, there is no evidence in Australia for using a peanut ball specifically for women using epidurals during labour.

This study will provide evidence about the effect of using the peanut ball for women who have an epidural during labour and be the first of its kind in Australia. It is envisaged that the results of this study will provide evidence for a larger randomised controlled trial in other hospitals in the Nepean and Blue Mountains Local Health District.

The aims of this pilot study are three-fold: the practicality of conducting a formal trial and information needed including recruitment rates, to determine whether using a peanut ball for pregnant women who have an epidural during labour makes clinically significant different outcomes and inform whether to conduct a larger randomised controlled trial (RCT) to establish clinical and statistical significance.

The peanut ball has only been recently used as a support for women labouring with epidurals in situ. Originally, the peanut ball had been used for physical therapy. The peanut ball is shaped like a peanut and fits snugly between the woman’s legs so that both legs are maintained as opening the pelvic outlet to increase the progress of labour and facilitate descent of the fetal head (Grant & Clutter, 2014).2

The peanut ball is shaped like a peanut shell where the middle circumference is smaller than the ends of the ball. In order to mimic the desired upright position during birth, the peanut ball can be used whilst the woman is in bed and the ball is supported by a pillow placed behind the woman’s hips to support her legs. Using position changes during labour to enhance widening of the pelvic outlet can be beneficial (Tussey, Botsios, Gerkin, Kelly, Gamez & Mensik, 2015)3 but a woman who has an epidural is limited in the number of positions she can adopt. The peanut ball is thought to enhance the progress of labour by optimally positioning the fetus in relation to the pelvis (Johnston, 1997).4

There are multiple benefits associated with maternal position changes, including increased maternal-fetal circulation, decreased pain, improved quality of uterine contractions, facilitation of fetal descent and decreased length of labour (Zwelling, 2010).5 Apart from the physiological benefits of birth, other benefits include less risk of postpartum haemorrhage (Davis, Baddock, Pairman et al., 2012),6 improved maternal–infant bonding (Moore, Anderson & Bergman 2007),7 less psychological morbidity postnatally (Michels, Kruske & Thompson 2013),8 increased rates of successful breastfeeding (Moore et al., 2007; Brown & Jordan, 2013) 9,10 and improved maternal satisfaction (Leap, Sandall, Buckland & Huber 2010). 11 The woman is also able to independently care for her baby following the birth, whereas women having a caesarean may require more assistance with feeding and general care of the baby. Therefore widening the pelvic outlet is one way of supporting natural progression of birth.

There is limited evidence on the use and effectiveness of a peanut ball for pregnant women during labour, especially in Australia. In fact, no randomised controlled trial has been implemented in Australia to establish the effectiveness of a peanut ball for labouring women. Three randomised control trials have been implemented in the United States of America on the use of a peanut ball during labour (Tussey et al., 2015; Roth, Dent, Parfitt, Hering & Bay, 2016; Evans & Cremering, 2016)3,12,13 and four randomized control trials were conducted in Brazil, Spain, Taiwan and Iran to establish the effect of a birthing ball, but not specifically a peanut ball (Makvandi, Roudsari, Sadeghi & Karimi, 2015).14

Of the three randomised control trials in the United States of America, one of the randomised control trials included women who were scheduled for elective induction of labour and also who used an epidural for labour pain. It was found that the length of time in first stage of labour was significantly shorter for primiparous (first time women having a baby) women using the peanut ball when compared with multiparous (having already had one baby) women and the peanut ball did not make any difference for either group in the time spent pushing (Roth et al., 2016).12

The other randomized control trial showed that women who used the peanut ball during labour had clinically significant lower caesarean section rates, lower instrumental births including forceps and vacuum births; and lower third and fourth degree perineal laceration rates. Even though the findings were clinically significant, they were not statistically significant. There was no difference in the length of stages of labour (Evans & Cremering, 2016).13 One of the randomised control trials showed that using the peanut ball was associated with a significantly lower incidence of caesarean surgery (OR = 0.41, p = .04) and is potentially a successful intervention to help progress labour and support vaginal birth for women labouring with an epidural anaesthesia (Tussey et al., 2015).3

Epidurals have been associated with higher interventions during labour, including a higher incidence of instrumental births (Anim-Somuah Smyth & Jones, 2011; Leighton & Halpern, 2002; Lieberman & O'Donoghue, 2002),15-17 especially in women having a baby for the first time (Comparative Obstetric Mobile Epidural Trial Study Group, 2001).18 Vacuum births have more than doubled in women experiencing epidurals (Anim-Somuah et al., 2011).15

Instrumental vaginal births are associated with an increased risk of perineal damage, urinary incontinence, painful sexual intercourse and bowel and sexual problems (Eason, Labrecque, Wells, & Feldman, 2000; Ekeus, Nilsson, & Gottvall, 2008; Groutz, Cohen, Gold, Hasson, Wengier, Lessing & Gordon, 2011).19-21 Instrumental vaginal births are also associated with adverse events in infants, such as cephalhaematoma or caput succedaneum and skull fractures with vacuum births (Simonson, Barlow, Dehennin, Sphel, Toppet, Murillo & Rozenberg, 2007).22

There are no expected harms in using the peanut ball intervention.

**Item No 6b**

The comparators will not use the peanut ball as we want to compare the outcomes between the group that uses the peanut ball and the group not using the peanut ball.

**Objectives Item no 7**

The aims of this pilot study are three-fold: the practicality of conducting a formal trial and information needed including recruitment rates, to determine whether using a peanut ball for pregnant women who have an epidural during labour makes clinically significant different outcomes and inform whether to conduct a larger randomised controlled trial (RCT) to establish clinical and statistical significance.

The assessment of endpoints is to determine if the peanut ball makes clinically significant different outcomes by comparing the intervention group that uses the peanut ball and the control group that does not use the peanut ball. Specifically it asks:

Is there a difference between women using the peanut ball and those who do not in the rate of vaginal births?

Is there a difference between women using the peanut ball and those who do not in the length of labour?

Is there a difference in health service usage between arms, regarding staff time, medications, procedures and length of stay in hospital. Is there a difference in experience in labour, including health related quality of life?

We hypothesise that placing the peanut ball between the labouring woman’s legs who has an epidural may facilitate the progress of labour (Tussey et al., 2015)3 and would be more likely to have a vaginal birth as opposed to a caesarean birth. We also hypothesise that women’s views about their own experience and health related quality of life will be more positive. Evidence of these outcomes will be evaluated more closely in the larger randomised control trial.

**Trial design Item no 8**

The allocation to intervention will be a randomised control trial. If the woman is assigned to the intervention group, she would participate in using the peanut birthing ball and if she is assigned to the control group, she would not use the peanut birthing ball. The assignment will include a single group where all participants in the intervention group receive the same intervention.

**Methods: Participants, interventions, and outcomes**

**Study setting Item no 9**

The data will be collected in Australia only at two sites- Blue Mountains Anzac District Memorial hospital and Lithgow hospital.

**Eligibility criteria Item no 10**

The sample will include women who are English speaking and non-English speaking, at least 36 weeks gestation with a live fetus and present with a cephalic presentation. Women will be excluded if they develop moderate to severe pre-eclampsia, or experience severe essential hypertension and if they are being treated for insulin dependent diabetes (gestational or pre-pregnant). Women will also be excluded if the fetal heart rate trace is abnormal or suspicious or if they experience an intra-uterine death.

**Interventions Item no 11a**

**Treatment schedule**

**Peanut ball** Women in this group will use the peanut ball during labour. Ideally the woman should commence using the peanut ball following insertion of the epidural, when the epidural has taken effect, so that the woman is comfortable and pain-free. It is important to change the woman’s position if she is using the peanut ball during labour with an epidural every 30 minutes. There are four main positions to be used with the woman having an epidural when she is using the peanut ball.

* ***The side lying position*** is when the woman is lying on her side and the peanut ball is wedged between her legs. The top leg lays on the top of the peanut ball curve and the bottom leg is bent underneath the peanut ball curve. The head of the bed is elevated as much as possible to ensure that the woman is comfortable.
* ***The tuck position*** is also a side lying position and the legs are pulled up towards the woman’s head and the ball is brought forward towards the woman’s chest so that the woman can hug the ball with her arms. The head of the bed should also be elevated as much as possible to ensure that the woman is comfortable. This position can also be used for pushing.
* ***The semi sitting position*** is when the woman is sitting semi recumbent and the top leg rests over the peanut ball over the natural curve and the bottom leg is bent and rests under the ball.
* ***The Taylor position*** is similar to the semi sitting position, although the legs squeeze the ball and the bottom leg moves up a bit higher towards the woman’s head.

**Not using peanut ball** The group of women not using the peanut ball will be provided the usual care during labour if using an epidural for pain relief.

**Item no 11b** Midwives have been directed to document any reasons why the woman discontinued using the peanut ball. Women will also be excluded if the fetal heart rate trace is abnormal or suspicious.

**Item no 11c** An education package for the use of a peanut ball during labour with an epidural specifically for this research project has been introduced for the midwives and doctors caring for the women using the peanut ball. The Chief Investigator will liaise with a site investigator to ensure appropriate allocation to a specific group.

**Item no 11d** No other concomitant care relevant during the trial

**Outcomes**

**Item no 12**

Baseline demographic data on age, education and year of birth will be collected from each woman participating in the study. Associated experiences and health related quality of life questions will be evaluated by the Health Questionnaire to both groups of women and an online survey will be distributed in the postnatal period to the women who used the peanut ball during labour to determine their satisfaction about using the peanut ball. All surveys are self-reported and all analyses will be performed blind to group allocation. Any information relating to the woman’s progress and comfort and effect of the peanut ball during labour with an epidural will be collected and details about other birth outcomes to determine baby’s condition, perineal damage, other methods of pain relief used, position of mother and baby during labour, cervical dilatation at time of insertion of epidural and evidence of augmentation and / or induction of labour.

**Primary vaginal birth outcome**

The primary outcome of this pilot trial will investigate the vaginal birth rate for women using the peanut ball and compare those not using the peanut ball. Epidurals have been associated with higher rates of instrumental births (Anim-Somuah Smyth & Jones, 2011; Leighton & Halpern, 2002; Lieberman & O'Donoghue, 2002)1-3, hence the importance and relevance of this particular outcome. Even though epidurals are effective in relaxing the pelvic floor during labour and facilitating the descent of the fetus into the pelvis, the natural mechanisms of birth are sometimes impeded, requiring instrumental intervention at that point when birth is imminent.

**Secondary length of labour outcome**

The secondary outcome will compare length of labour for women using the peanut ball and compare those not using the peanut ball. The length of labour for women who are multiparous (having more than one baby) is usually shorter than for those women who are primiparous (having first baby). A previous randomised control trial found that the length of time in first stage of labour was significantly shorter for primiparous (having first baby) women using the peanut ball when compared with multiparous (having subsequent baby) women and the peanut ball did not make any difference for either group in the time spent pushing (Roth et al., 2016)12. The length of labour will report first, second and third stages of labour. First stage of labour measures commencement of regular uterine contractions and cervical dilatation until full dilatation of the cervix. Second stage of labour measures the time from full dilatation of the cervix to following the birth of the baby, including length of time pushing. Third stage of labour measures the time following the birth of the baby to completion of placental birth. The fourth stage of labour will assess the time of the first feed, the type of feed and if skin to skin contact was initiated.

**Health and satisfaction assessments**

1. The Health Questionnaire will provide important general physical and mental health information about mobility, self-care, usual activities, (for example, work, study, housework, family or leisure activities), pain, discomfort, anxiety and depression. The Health Questionnaire will also request a single score about level of health experienced on that particular day.
2. The survey assessing satisfaction levels about using the peanut ball will enquire about benefits of using the peanut ball, subsequent use of the peanut ball, whether the woman would recommend using the peanut ball to other women and reasons why, discomfort, specific positions used with the peanut ball, experiencing feelings of empowerment and effect on length of labour.

**Birth outcomes**

Details about other birth outcomes will also be collected to determine baby’s condition, perineal damage, other methods of pain relief used, position of mother and baby during labour, blood loss, cervical dilatation at time of insertion of epidural and evidence of augmentation and / or induction of labour.

**Economic measures**

Assessments will establish health service usage between arms, staff time, medications, procedures and length of stay in hospital.

**Participant timeline**

**Item no 13**

|  |  |
| --- | --- |
|  |  **STUDY PERIOD** |
|  | Enrolment | Allocation | Primip / multip | Other pain relief | Aug/induced | Apgars | Perineum | Position of woman | Cervical dilation at time of epidural insertin | Length of stay |
| **TIMEPOINT** | During labour | During labour |  |  |  |  |  |  |  |  |
| **ENROLMENT:****Eligibility screen****Informed consent****Allocation** | XX | X |  |  |  |  |  |  |  |  |
| **INTERVENTIONS:****Intervention** **Comparator group** |  | X or X |  |  |  |  |  |  |  |  |
| **ASSESSMENTS****Primary outcome****Secondary Outcome****Other variables** |  | XXX | X | X | X | X | X | X | X | X |

**Sample size**

**Item no 14**

To reiterate, the main aims for this pilot study are three-fold: the practicality of conducting a formal trial and information needed including recruitment rates, to determine whether using a peanut ball for pregnant women who have an epidural during labour makes clinically significant different outcomes and inform whether to conduct a larger randomised controlled trial (RCT) to establish clinical and statistical significance. Nonetheless, a previous pilot study that investigated the use of the peanut ball with similar aims determined that approximately 50 pregnant women were required to demonstrate statistically significant findings (Tussey et al., 2015)3 Given the high feasibility of recruiting these numbers of women at the study sites, a decision was made to aim for 50 in total (as a minimum) and opt for a comprehensive pilot trial.

Modifications may be made to the protocol for the full trial based on recruitment rates.

**Recruitment**

**Item no 15**

Advertisements will be displayed in the Lithgow and Blue Mountains Anzac District Memorial hospital antenatal clinics and distributed to women in antenatal classes about the opportunity for pregnant women to participate in the research if they use epidurals for pain relief during labour. Women will be requested to contact the Coordinating Investigator via email, to express their interest in participating in the research project.

The participants will be identified and approached and consented during labour if they have an epidural.

**Methods: Assignment of Interventions (for controlled trials)**

**Allocation:**

**Sequence generation Item no 16a**

Random order generation is being done by simple randomisation (created by computer software).

**Allocation concealment mechanism Item no 16b**

Allocation is concealed by sealed opaque envelopes.

**Implementation Item no 16c**

Practitioners and participants will know the allocation group for the women, as the woman will either use the peanut ball or not use the peanut ball, so they will not be blinded. A computerised, internet-based central randomisation service (sealedenvelope.com) will be used to provide randomisation and allocation concealment. The research assistant and other investigators performing data collection, entry and analysis will be blind to group allocation. The women will be randomly assigned to either the control or intervention group by the random allocation selection process that will involve sealed opaque envelopes that only the midwife opens once the woman consents to be involved in the pilot study. Once known, the chief investigator will communicate the group allocation to the participant.

**Blinding (masking) Item no 17a**

Blinded masking will be used for the people analysing the results / data (data analyst).

**Item no 17b**

The midwives recruiting the women will not be blinded as to the allocation to either intervention or control group. The participants will not be blinded as they will know the allocation to using the peanut ball in the intervention group or not using the peanut ball in the control group. Only the researchers analysing the results will be blinded to what group they are analysing.

**Methods: Data collection, management and analysis**

**Data collection methods Item no 18a**

The data for this research project will be collected by accessing the maternity database E-Maternity to record all women’s outcomes for those women in the control and in the intervention groups. The women who use the peanut ball during labour will be asked a short survey in the postnatal period to determine their satisfaction about using the peanut ball. Both groups will also be sent a survey about their general health.

**Item no 18b**

The data for this research project will be collected by accessing the maternity database E-Maternity to record all women’s outcomes for those women in the control and in the intervention groups. The online survey will be sent to the woman via email using the Qualtrics software to be completed in the postnatal period. If the woman has not responded within ten days, one reminder email will be sent.

**Data management Item no 19**

All of the data collected will be stored in a password protected computer and will only be accessible by the researchers. This data will be recorded in SPSS (Statistical Package for Social Sciences) – a statistical package for analysis. Qualtrics will only be able to be accessed by the researchers and is password protected. This data will be located in a Centre for Nursing and Midwifery Research. All data will be de-identified and destroyed after a 15 year period.

**Statistical methods Item no 20a**

Demographics will be reported using descriptive statistics. To reiterate, the main aims for this pilot study are to assess recruitment techniques and detect potentially clinically significant differences that would warrant further investigation in a larger randomised control trial.

It is not the main aim of the pilot to obtain statistically significant results for the clinical outcomes. Nonetheless, standard statistical techniques will be undertaken as would be if going to full trial, for exposition, and online survey results will provide complementary data from the woman’s perspective of using the peanut ball during labour and health and quality of life. Regarding statistical tests, independent t tests and Chi-square analyses will be used to determine differences between the two groups.

Economic measures and analysis

An economic analysis will be conducted alongside the trial to establish feasibility of economic data collection, provide indicative cost effectiveness results, and to inform whether investment in a larger definitive trial is value for money. Across both trial arms, health service use, staff time, medications, associated procedures, and length of stay in hospital will be measured over one year. Further, economic measure of health related quality of life, the EQ5D5D, will assess health utilities between trial arms.

It is hypothesised that the peanut ball will lead to clinically significant results in most women but given the small trial size there will likely be considerable statistical uncertainty regarding mean cost effectiveness. Statistical uncertainty will likely be driven by variation in clinical outcomes, costs, and health utilities. The consequence of uncertainty is the risk of making a wrong decision whether to accept / reject the peanut ball in routine practice. Therefore, following international best practice guidelines (Caro, Briggs, Siebert & Kuntz, 2012),23 this uncertainty will be thoroughly investigated with a view to assess the need for further research. First, a probability sensitivity analysis will identify the key drivers of uncertainty, including parameter and heterogeneity. Next, a value of information (VOI) analysis will convert statistical uncertainty, whether the peanut ball is cost effective, into dollar values. This represents the ‘opportunity cost’ of a wrong decision (e.g. reject peanut ball) that leads to lower clinical outcomes, lower quality of life, and higher health service costs. This dollar value represents the business-case whether investing in a definitive trial (and what size of trial) is justified to reduce uncertainty and increase confidence that the peanut ball is, not only clinically effective, but also cost effective.

**Item no 20b**

Demographic data will be summarised including age, education and country of birth by descriptive statistics.

**Item no 20c**

The pilot study will follow an intention to treat analysis, whereby all participants’ information in the study will be included.

**Methods: Monitoring**

**Data monitoring Item no 21a**

A data monitoring committee is not needed as the Chief Investigator and Research Assistant will be working in collaboration closely to clean the data and monitor the incoming data.

**Item no 21b**

The Chief Investigator will have access to the preliminary, interim and final results and make the final decision to terminate the trial based on sufficient sample size and preliminary results to substantiate a larger randomised control trial.

**Harms Item no 22**

If the woman suffers any distress or psychological injury as a result of this research project, she

should contact the research team as soon as possible.   She will be assisted with arranging

appropriate treatment and support.

**Auditing Item no 23**

No extra auditing will be executed due to the small sample size that will be able to be managed by the researchers.

**Ethics and dissemination**

**Research ethics approval Item no 24**

The research protocol has been submitted to the Nepean Blue Mountains Local Health District and has been approved.

**Protocol amendments Item no 25**

All modifications to the protocol will be communicated to all the investigators on the project.

**Consent or assent Item 26a**

Advertisements will be displayed in the Lithgow and Blue Mountains Anzac District Memorial hospital antenatal clinics and distributed to women in antenatal classes about the opportunity for pregnant women to participate in the research if they use epidurals for pain relief during labour. Women will be requested to contact the Coordinating Investigator via email, to express their interest in participating in the research project. The Coordinating Investigator will liaise with midwives at the sites about women who have consented by email. The Coordinating Investigator will access the woman’s due date via E-maternity database and this information will be provided to midwives at each site via the maternity manager, so that midwives know women who have expressed interest in the study prior to their birthing experience. As well as these women (who may not use epidurals during labour) the participants will be identified and approached and consented during labour by the midwives at each site if they have an epidural in labour. Midwives have been educated about these processes at each site and they will have research boxes with the available information and consent forms to access for any women having epidurals. They will also have access to separate boxes that will contain the sealed opaque envelopes that will determine the allocation to either control or intervention group. If the woman is allocated to the control group, she will have usual care in labour and if allocated to the intervention group, she will use the peanut ball in labour.

The participants will be identified and approached and consented during labour if they have an epidural. The women who fit the inclusion criteria will be provided a participant information sheet and then asked to sign a participant consent by the midwife not involved in her care.

**Item 26b**

N/A

**Confidentiality Item 27**

All data will be de-identified and destroyed after a 15 year period and will only be shared by the research team until the research project is complete.

**Declaration of interests Item no 28**

N/A

**Access to data Item 29**

The Chief Investigator will have access to the final trial dataset, no contractual agreements in place.

**Ancillary and post-trial care Item no 30**

N/A

**Dissemination policy Item no 31a**

Pregnant women who have identified that they would be interested in the research results on their consent form, will be provided an overall report on the research results in layman’s terms.

**Item no 31b**

N/A

**Item no 31c**

N/A

**Informed consent materials Item 32**

The participant will be provided with a participant informed consent form and possibility to withdraw (see attached Participant Information Consent form).

**Biological specimens Item 33**

N/A

**References**

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