

# Ethical review process: a case study



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## **Ethical review of Case Study 2.**

### **Analysis of case study 2: Study design:**

This study aims to assess the following primary objectives:

- Maternal and infant feeding practices.
- Nutrition advice to Caucasian low-income post-partum women that receive Healthy Start vouchers
- Nutrition advice to general population of Pakistani women.

However, it also aims to assess other secondary objectives including:

- Dietary intakes of Caucasian low-income post-partum women receiving Healthy Start vouchers using a validated Food Frequency Questionnaire (FFQ).
- Diet of the general population of Pakistani post-partum women using 24hr. dietary recalls.
- Determine influences on breastfeeding initiation, duration and weaning practices in Caucasian post-partum women receiving Healthy Start

vouchers and of the general population of post-partum Pakistani women.

- Determine how area of deprivation, ethnicity, maternal age, educational level, dietary intake, cooking ability and shopping behaviour influence infant feeding practices.
- Determine whether the introduction of Healthy start vouchers will have an effect on the nutrient intakes and eating patterns of new mothers and their infants.
- Determine if dietary information recommended under the Healthy Start initiative to low-income new mothers is delivered.

Design: The study will be conducted similarly for both ethnic groups. The participating mothers will be contacted to arrange for a home visit (face-to-face interview) where a member of the nutrition research team (NRT) will administer a validated subject information questionnaire (SIQ) and an infant feeding questionnaire (IFQ). For the Pakistani women a 24-hr recall will also be performed during the home visits whereas for the Caucasian women a food frequency questionnaire (FFQ) will be performed during the home visits. . Thereafter, an IFQ will be administered to both ethnic groups by a member of the NRT over the telephone at 2, 3, 4, 5, 6, 9 and 12 months post-partum. During these phone interviews the Pakistani population will also undergo a 24-hr recall whereas the Caucasian population will undergo an FFQ.

Validity of research methods: Telephone interviews with relevant questionnaires are acceptable methods to gather enough information to answer the questions and objectives. However, validated questionnaires are required to assess their adequacy to answer the research questions. The

face-to-face interview (home visit) might not be a valid method of assessment as the mother might be unfocused (constantly thinking on the wellbeing of the child) and uneasy especially if she is alone with the interviewer. This in turn could lead to possible risks and insurance issues to the researchers.

Sample Size: The data presented only contained a range of how many participants will participate in each cohort (Caucasians -200-250, Pakistani – 150-200). There was no information whether the lower limit of the ranges was the actual sample size needed. Also, there is no data on how these ranges were obtained, no power calculation or data on how this was performed were included. In addition, as the ranges

### **Analysis of discussion board**

From the start, all taking part in the committee noticed several discrepancies in the study. Primarily, we all noticed that there is no prior mentioning on how the researchers got permission to access (with the help of a midwife) potential participants medical notes. This raises serious doubt on the researchers eligibility to filter among potential participants before these could be contacted and asked for consent.

I am also doubtful on why the Pakistani women are being selected. Are these being used as a representative for ethnic minorities which are on low incomes? There was no claim for this in the application and would therefore need further backing from literature or relevant statistics.

The personal information sheet (PIS) is easy to understand and clear, however in some verses it was deemed to be informal (ex. “ you may have <https://assignbuster.com/ethical-review-process-a-case-study/>

to pay for it”), misleading, as in the PIS the participant is told that the data collected will be destroyed. However, in this application it is claimed that data will be stored for 5 years prior to destruction. In the PIS it is claimed that the study will be used to develop a screening tool, however this does not feature in the long list of aims and objectives presented in this application. In addition, there is no mention on what happens to data collected from participants if they eventually withdraw from the study, if data can be used by other researchers or even by third parties or on what criteria where these mothers contacted for participation. This could lead to a breach in confidentiality and may have been omitted as participation rates could suffer, nevertheless this needs further clarification and amending.

Other questions have arisen on the study design, I was not convinced by the long list of objectives the study has as it makes the study unfocused. The 24-hour recall method used to collect data from Pakistani women only, is not explained and cannot be assessed on its validity for the study or whether needs ethical consideration.

Anonymity and confidentiality was another issue raised. Although the researcher claims that confidentiality will be maintained at all times with each participant being assigned a code to maintain confidentiality, each participant will have her phone number and address recorded for the interviews, which could give the opposite result. This is further enhanced since in one cohort a minority group is being assessed and participants can be easily identify.

## Feedback to Researchers

- Provisional opinion (Sub-committee)
  - (changes required documentation)
- Provide copies of all questionnaires (validated).
- Why different questionnaires are used for the two population cohorts?  
Different methods used may give non-comparable results.
- Has proper permission from the potential participants been sought to filter through patient medical notes? Please provide any declarations or permission forms which state this.
- Can and will data gathered from this research be accessible by other potential researchers any third parties?
- How many participants are required to participate in the study? Include data on how power calculation was performed.
- Please provide information on how the 24-hour recall will be performed, what questions will be asked and provide the validated questionnaire that will be used.
- Include the following additional information in the PIS:
  - Data storage time after study is complete.
  - Why the participants have been approached and contacted for this study.
  - Some sections need rewording as they can be deemed as informal or inappropriate (eg. “ You may have to pay for it”).
  - Clarify whether the study will be used to develop a screening tool as this is not mentioned in the aims of the study.

- Include whether data can be accessed by other potential researchers or third parties in the 5 year time window after study has been conducted.
- Address syntax errors in the inclusion and exclusion criteria used as these are the complete opposite of what the study is trying to achieve.
- Why are only Pakistani women included in one of the population cohorts? What is there significance?
- It is advised to focus on fewer aims and objectives to make the study more focused and retain better results.
- What happens to the data if participant withdraws from study?
- Why is data retained for 5 years before being destroyed? Why is this not stated in the PIS? Can data be retrieved by other potential researchers or third parties?
- The PIS states that the study will also be used to develop a screening tool, why is this not stated in the aims and objectives of the study?
- What is the potential to use home visits? Will this be beneficial or allow for more distress to the mother? Especially if she is alone.
- In the case that new mothers in both cohorts are found to need further care, is the advice extended to them even after the study is complete?

## **Ethical Issues:**

Social or The

Scientific introductio

value n of

Healthy

Start

vouchers  
has helped  
low-income  
mothers to  
improve  
diet and  
feeding  
habits as  
these are  
deemed to  
be  
important  
for the  
developing  
child as it  
will help  
him decide  
what food  
is better for  
them. This  
study will  
help  
provide  
evidence to  
improve  
guidelines



and also  
improve  
dietary  
advice  
given to  
these  
vulnerable  
mothers.

### Scientific Phone

validity interviews  
and  
questionnai  
res are  
deemed an  
acceptabl  
e method  
to collect  
data for  
this study.  
However,  
face-to-face  
interviews  
(home  
visits)  
might not

be as  
beneficial  
as stated  
as they  
might  
cause more  
distress to  
the mother.

Fair      The  
participa      research  
nt              team  
selection      stated that  
the study  
conducted  
will ensure  
that  
participant  
confidential  
ity will be  
maintained  
by  
assigning a  
code to  
each  
participant.

However,  
recording  
of phone  
numbers  
and  
addresses  
as will be  
necessary  
to conduct  
face-to-face  
and  
telephone  
interviews  
might not  
aid in this  
process  
especially  
with regard  
of the child.

Favorabl  
e risk  
benefit  
ratio  
The study  
will has the  
potential of  
achieving  
evidence  
that will in

the future  
give better  
advice to  
future new  
mothers  
that might  
be at risk.  
However,  
certain  
shortcomin  
gs still  
need  
attention.

#### Informed Oral

consent consent will  
first be  
sought  
from the  
participant,  
written  
consent will  
then be  
sought for  
the new  
mothers to

participate  
in the  
study.  
However,  
no  
information  
regarding  
consent in  
accessing  
potential  
participant  
medical  
notes has  
been  
presented.

Respect Home visits  
for might be  
potential deemed as  
and a distress  
enrolled for the new  
participa mothers as  
nts they will  
have to  
undergo an  
interview in

their own

home

which

might be

uneasy.

Also,

access to

the

participants

medical

notes with

prior

consent is a

complete

breach of

confidential

ity and

respect.