ISRCTN60994059 https://doi.org/10.1186/ISRCTN60994059

Caricature-based Antenatal BreastFeeding Education Trial (CABFET)

Submission date
15/07/2022

Recruitment status
No longer recruiting

Registration date
19/07/2022

Overall study status
Completed

Last Edited
28/05/2024

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Antenatal breastfeeding education is essential in supporting future mothers to breastfeed their newborns. Nowadays, health care professionals are innovating teaching methods and using technology in patient education to gain patient satisfaction and change their behaviors. Therefore, this clinical trial aims to examine the effect of caricature-based breastfeeding education in increasing exclusive breastfeeding practice and reducing the unnecessary use of milk formula.

Who can participate?
Pregnant women in the second or third trimester who attend follow-up in primary care centers belonging to Riyadh First Health Cluster (C1) in Saudi Arabia.

What does the study involve?
Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). One group will receive caricature-based online lectures on breastfeeding for 2 hours, while the other group will receive a 1-hour standard online lecture on breastfeeding. All participants will be provided a paper booklet on breastfeeding. Participants will be followed up until 3 months after delivery using electronic Google surveys delivered via WhatsApp.

What are the possible benefits and risks of participating?
The pregnant women who join the study as participants will benefit from the educational sessions. There is no expected harm to them and their data will be kept confidential.

Where is the study run from?
Ministry of Health (Saudi Arabia)

When is the study starting and how long is it expected to run for?
September 2020 to December 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Dr Fouzia Alhreashy; fouziaalhreashy@yahoo.com
2. Arwa Mobeirek; Arwa.Mobeirek@gmail.com

Contact information

Type(s)
Scientific

Contact name
Ms Arwa Mobeirek

Contact details
Ministry of Health
Riyadh
Saudi Arabia
13216
-
Arwa.Mobeirek@gmail.com

Type(s)
Scientific

Contact name
Dr Fouzia Alhreashy

ORCID ID
https://orcid.org/0000-0003-3329-7640

Contact details
Ministry of Health
Riyadh
Saudi Arabia
13216
-
falhreashy@moh.gov.sa

Additional identifiers

Study information

Scientific Title
Caricature-based antenatal breastfeeding education: a randomized controlled trial

Acronym
CABFET

Study objectives

Caricature-based antenatal breastfeeding education will increase exclusive breastfeeding rate at one month and 3 months postpartum by 17%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/03/2021, King Saud Medical City Institutional Review Board Committee (Imam Abdul Aziz Ibn Muhammad Ibn Saud, Ulaishah, Riyadh; +966 435 5555 ext. 2345; irb@ksmc.med.sa), ref: H1RI-10-Mar21-01

Primary study design
Interventional

Study design
Single-center interventional single-blinded randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Antenatal breastfeeding education

Interventions
Previous: Random allocation to intervention or control groups was done via randomizer.org.

Updated 02/08/2022: Participants were randomly assigned to the intervention or control arms in a 1:1 ratio using computerized random numbers.

The intervention group received two caricature-based lectures on breastfeeding (2 hours). The control group received one standard lecture on breastfeeding (1 hour). Both groups received a breastfeeding paper booklet.

There will be 4 follow-up points of data collection.
First follow-up (during pregnancy before the intervention): sociodemographic data and intention to breastfeed
Second follow-up (during pregnancy after the intervention): prenatal breastfeeding self-efficacy scale and satisfaction about health education
Third follow-up (1 month postpartum): infant feeding practice and breastfeeding self-efficacy scale – short form
Fourth follow-up (3 months postpartum): infant feeding practice and Iowa infant feeding attitude scale

Intervention Type
Behavioural

Primary outcome(s)
Exclusive breastfeeding measured using electronic Google surveys on infant feeding practice delivered via WhatsApp at 1 and 3 months postpartum

Key secondary outcome(s)
1. Prenatal breastfeeding self-efficacy measured using the prenatal breastfeeding self-efficacy scale during pregnancy after the intervention
2. Maternal satisfaction about the health education measured using the satisfaction about health education questionnaire during pregnancy after the intervention
3. Postpartum breastfeeding self-efficacy measured using the breastfeeding self-efficacy scale – short form at 1 month postpartum
4. Infant feeding attitude measured using the Iowa infant feeding attitude scale at 3 months postpartum

Completion date
01/12/2022

Eligibility

Key inclusion criteria
1. Aged >18 years
2. Pregnant women in the second or third trimesters
3. Receiving antenatal care in Riyadh First Health Cluster (C1)
4. No contraindication to breastfeeding
5. Have access to the internet
6. Literate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Total final enrolment
85

Key exclusion criteria
1. Pregnant women in the first trimester
2. Contraindication to breastfeeding
3. No access to internet
4. Illiterate

Date of first enrolment
01/05/2021

Date of final enrolment
01/05/2022

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Riyadh First Health Cluster (C1)
6th floor
North Wing
Gate D
Al Akaria Plaza
Riyadh
Saudi Arabia
11622

Sponsor information

Organisation
Ministry of Health

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Data sharing statement to be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/04/2024	28/05/2024	Yes	No