

Caricature-based Antenatal BreastFeeding Education Trial (CABFET)

Submission date 15/07/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/07/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 28/05/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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
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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

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

Study design

Single-center interventional single-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2020

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

270

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

Sponsor details

Digital City
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Sponsor type

Government

Website

<https://www.moh.gov.sa/>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

01/01/2023

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