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Digital intervention for tokophobia: a randomized controlled trial of internet-based cognitive behavioral therapy on fear of childbirth and self-efficacy among Egyptian pregnant women

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Abstract

Background Tokophobia affects up to 14% of pregnant women globally and is linked to high cesarean rates, particularly in Egypt. This study evaluated the efficacy of a culturally adapted Internet-based Cognitive Behavioral Therapy program on fear of childbirth and maternal self-efficacy among Egyptian pregnant women.

Methods A randomized controlled trial was conducted in Damanhur City, Egypt, involving 96 pregnant women with moderate to severe tokophobia. Participants were randomly assigned to an intervention group (n=48) receiving a six-week program via WhatsApp or a control group (n=48) receiving routine antenatal care. The intervention included cognitive restructuring, exposure therapy, relaxation techniques, and psychoeducation grounded in Bandura's Self-Efficacy Theory. Outcomes were assessed using the Childbirth Attitude Questionnaire and Childbirth Self-Efficacy Inventory at baseline and post-intervention.

Results Post-intervention, the intervention group demonstrated a significant reduction in fear of childbirth scores (mean decrease: 14.32 ± 5.55 ; p < 0.001) and an increase in maternal self-efficacy (mean increase: 38.3 ± 35.7 ; p < 0.001). Large effect sizes were observed for both fear reduction ($\eta^2 = 0.876$) and self-efficacy enhancement ($\eta^2 = 0.600$). The control group showed no significant changes.

Conclusion The culturally adapted Internet-based Cognitive Behavioral Therapy program significantly reduced tokophobia and enhanced maternal self-efficacy, supporting its integration into perinatal care. These findings align with Bandura's Self-Efficacy Theory and suggest the potential of digital interventions in improving psychological outcomes, especially in resource-limited settings.

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Implications for practice Integrating the program into routine antenatal care could provide accessible, cost-effective support for women experiencing tokophobia, potentially reducing unnecessary cesarean sections and informing health policy regarding the effectiveness of the ICBT program. Future research should assess long-term outcomes and generalizability in diverse populations.

Trial Registration The study was registered on ClinicalTrials.gov under the identifier (NCT06640608) on October 15, 2024

Keywords Fear of childbirth, Tokophobia, Internet-based cognitive behavioral therapy, Self-efficacy, Randomized controlled trial, Egyptian pregnant women

Introduction

Fear of childbirth, medically termed tokophobia, is a significant psychological concern affecting pregnant women globally [1–3], with profound implications for maternal mental health and pregnancy outcomes [4, 5]. Tokophobia manifests as an intense fear or dread of labour and delivery, often leading to heightened anxiety, avoidance behaviours, and increased requests for elective cesarean sections without medical indications [6–8]. The prevalence of tokophobia varies across populations, with studies indicating that approximately 14–22% of pregnant women experience significant fear of childbirth, and severe fear affects about 6–10%. Addressing this fear is crucial for promoting positive childbirth experiences and improving both maternal and neonatal health outcomes [9, 10].

In the Egyptian context, tokophobia presents as a pressing public health issue influenced by specific cultural, social, and healthcare factors. Egypt has witnessed one of the highest cesarean section rates globally, with a significant increase from 27.6% in 2008 to approximately 51.8% in 2014, as reported by the Egypt Demographic and Health Survey (EDHS) [11, 12]. Recent estimates suggest this rate has continued to rise, reaching over 54% in some regions [13]. This dramatic escalation indicates that fear of childbirth may be a substantial contributing factor, as many women opt for cesarean delivery due to anxiety about labour pain, perceived safety concerns, and distrust in the quality of maternity care [14–17]. Cultural beliefs and societal norms in Egypt significantly shape women's perceptions of childbirth, with misconceptions often reinforced by media portrayals and anecdotal experiences shared within communities, exacerbating existing fears [18, 19]. The lack of comprehensive antenatal education and limited communication between healthcare providers and expectant mothers further contribute to misinformation and heightened anxiety [20]. Additionally, factors such as previous traumatic birth experiences, low socioeconomic status, and inadequate support systems intensify tokophobia, particularly among primigravida women [21, 22].

This study is grounded in Bandura's Self-Efficacy Theory [23, 24], which posits that an individual's belief in their ability to execute behaviors necessary to produce specific performance attainments influences their actions, motivation, and psychological states [25, 26]Self-efficacy relates to a woman's confidence in her capacity to cope with labor and delivery challenges [27]. Higher levels of childbirth self-efficacy are associated with reduced fear, effective stress management, and positive birth experiences [28]. Enhancing self-efficacy empowers women to adopt adaptive coping strategies, mitigating anxiety and promoting better maternal and neonatal outcomes [29, 30].

Cognitive Behavioral Therapy (CBT) has emerged as an evidence-based psychological intervention focusing on identifying and modifying negative thought patterns and behaviors to improve emotional regulation and develop effective coping mechanisms. When applied to tokophobia [31, 32], CBT targets irrational fears and maladaptive beliefs about childbirth, fostering resilience and adaptive coping [33]. The advent of digital technology has facilitated the delivery of CBT through online platforms, known as Internet-based Cognitive Behavioral Therapy (ICBT) [34, 35], enhancing accessibility and flexibility for users [36]. ICBT offers several advantages, particularly in regions like Egypt [30], where access to mental health services may be limited due to geographical, economic, or societal barriers [37, 38]. It allows women to engage with therapeutic content at their convenience, overcoming obstacles such as transportation difficulties, scheduling conflicts, and the stigma associated with seeking psychological support [39, 40]. The anonymity provided by online interventions can encourage more open expression of fears and concerns, which is crucial for effective therapy [41, 42].

Recent studies have demonstrated the efficacy of ICBT in reducing fear of childbirth and enhancing self-efficacy [43, 44]. However, research specifically examining ICBT for tokophobia within the Egyptian context is scarce [45, 46]. Cultural differences, language barriers, and variations in healthcare infrastructure necessitate culturally adapted interventions tailored to the unique needs of Egyptian women [47]. To date, no known studies have evaluated the effectiveness of ICBT programs targeting

fear of childbirth among pregnant women in Egypt, highlighting a critical gap in the literature [47, 48].

This study aims to fill this gap by evaluating the efficacy of an Internet-based Cognitive Behavioral Therapy program designed to reduce fear of childbirth and enhance self-efficacy among Egyptian pregnant women experiencing moderate to severe tokophobia. The study examines several key variables, including participation in the ICBT intervention (independent variable), levels of fear of childbirth measured by the Childbirth Attitude Questionnaire (CAQ), and maternal self-efficacy assessed using the Childbirth Self-Efficacy Inventory (CBSEI) as dependent variables. Controlled variables include demographic factors, obstetric history, and exclusion criteria such as diagnosed mental health disorders and pregnancy complications.

The significance of this study lies in its potential contributions to the field of maternal mental health and clinical practice in Egypt. First, it provides empirical evidence on the effectiveness of a culturally adapted ICBT intervention for tokophobia, offering a novel approach to address a prevalent issue. Second, the findings may inform healthcare policies, promoting the integration of mental health support into routine antenatal care. Third, by potentially reducing unnecessary cesarean sections, the study addresses public health concerns related to surgical risks, healthcare costs, and resource allocation.

Based on the theoretical framework and existing literature, the study proposes two main hypotheses:

H1: Pregnant women who receive the ICBT intervention will report a significant reduction in

- mean scores of fear of childbirth compared to those receiving routine antenatal care.
- H2: Pregnant women who receive the ICBT intervention will report a significant increase in mean scores of maternal self-efficacy compared to those receiving routine antenatal care.

Figure 1 illustrates this study's theoretical framework and its connection to the research hypotheses. The diagram demonstrates how Bandura's Self-Efficacy Theory and Cognitive Behavioral Therapy in form the Internet-based CBT intervention, which is expected to reduce fear of childbirth and enhance maternal self-efficacy. These anticipated outcomes directly correspond to the study's main hypotheses.

The long-term implications of reducing tokophobia are substantial [49, 50]. Women who overcome the fear of childbirth are more likely to have positive birth experiences, which can enhance maternal-infant bonding and attachment [44, 51, 52]. Improved self-efficacy and reduced anxiety may decrease the risk of postpartum depression and anxiety disorders [28]. These outcomes not only benefit the mothers but also have positive implications for child development and family dynamics and potentially contribute to reducing the high cesarean section rates in Egypt [47].

In conclusion, fear of childbirth is a prevalent and impactful concern among Egyptian pregnant women, influenced by complex cultural, social, and healthcare factors. Leveraging Internet-based Cognitive Behavioral Therapy grounded in self-efficacy theory presents a promising approach to addressing tokophobia. This study seeks to evaluate the effectiveness of such an

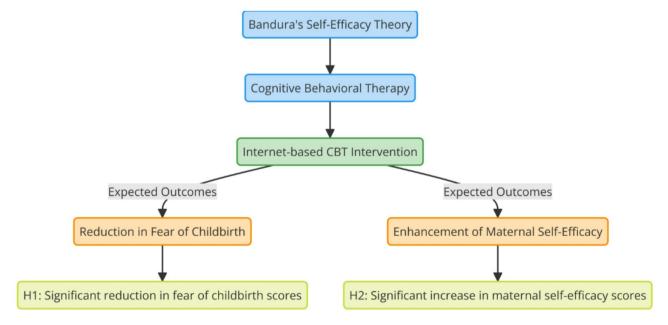


Fig. 1 Conceptual model of internet-based cognitive behavioral therapy for tokophobia: theoretical framework and hypotheses

intervention, aiming to contribute valuable insights to the field, inform clinical practice, and ultimately improve maternal and neonatal health outcomes in Egypt. By addressing the identified research gap, this research can influence healthcare strategies, promote the integration of mental health support into antenatal care, and empower women to approach childbirth confidently. The findings may serve as a foundation for future research and the development of targeted interventions in similar cultural contexts, fostering healthier generations to come

Materials and methods

Research design and setting

This study utilized a parallel, randomized, controlled, single-blind design between August 2023 and December 2023. The researchers conducting data analysis and outcome assessments were blinded to group allocation, which minimized bias in assessing the intervention's effectiveness.

The present study represents the second phase of a broader research initiative titled "Overcoming Childbirth Fear Among a Sample of Egyptian Pregnant Women." The initial phase involved a comprehensive cross-sectional analysis aimed at identifying the prevalence and determinants of fear of childbirth (tokophobia) among Egyptian pregnant women. The analysis found that 169 participants experienced moderate to severe levels of fear. Of these, 96 women met the inclusion criteria for the subsequent intervention phase of the trial.

The primary objective of the current RCT was to assess the efficacy of Internet-based Cognitive Behavioral Therapy (ICBT) compared to routine antenatal care. The intervention group received ICBT in addition to routine antenatal care, while the control group received routine antenatal care only. The control and intervention group participants received the routine antenatal care offered by the Egyptian health system. Routine antenatal care included follow-up prenatal consultations, obstetric physical exams, monitoring of fetal growth, nutrition education, and maternal health. These services were provided at Damanhour General Hospital's antenatal clinic and three MCH centers.

This design facilitates a robust evaluation of the ICBT intervention's effectiveness in reducing childbirth-related fear and enhancing maternal self-efficacy, grounded in Bandura's Self-Efficacy Theory. Using a parallel group design ensured that each participant group was exposed to distinct treatment conditions, thus enabling a direct comparison of outcomes related to fear reduction and self-efficacy enhancement.

The study was conducted in Damanhur City, located within the El-Beheira Governorate in Egypt. Multiple recruitment sites were utilized to ensure a representative and socioeconomically diverse sample. These included antenatal clinics at Damanhour General Hospital and three Maternal and Child Health (MCH) centers: Nasser Medical Center, Al-Helal Center, and Abo-Alresh Health Center. The selection of these sites was informed by their geographical distribution and the varied socioeconomic backgrounds of the populations they serve, thereby enhancing the external validity and generalizability of the findings to a broader demographic of Egyptian pregnant women.

The research was meticulously designed to span five months (August 2023 to December 2023), a duration that allowed for comprehensive participant recruitment, intervention delivery, and follow-up assessments. The study timeline also considered seasonal fluctuations in healthcare utilization patterns and potential variations in participant availability. This study adhered to the CONSORT (Consolidated Standards of Reporting Trials) guidelines for reporting randomized controlled trials.

Participant sample size determination

The sample size for this randomized controlled trial was determined based on a power analysis to detect a statistically significant difference in fear of childbirth reduction between the intervention and control groups. The primary outcome measure was the change in scores on the Childbirth Attitude Questionnaire (CAQ) from baseline (T1) to post-intervention (T2). A moderate effect size (Cohen's d=0.5) was assumed based on previous studies evaluating the effectiveness of Cognitive Behavioral Therapy (CBT) in reducing childbirth fear. The analysis was conducted with a significance level (alpha) of 0.05 and a power of 80%, which is the conventional standard for clinical trials to minimize the risk of Type II error (failing to detect a true effect).

Using these parameters, the required sample size was estimated to be 86 participants, with 43 women needed in each group to ensure adequate statistical power. To account for potential attrition, such as participants dropping out of the study or failing to complete the intervention, the sample size was inflated by 10%, leading to a target enrollment of 96 participants (48 in the intervention group and 48 in the control group).

Out of 169 women initially screened for moderate to severe fear of childbirth, 96 met the eligibility criteria and consented to participate in the study. These participants were then randomly allocated to either the ICBT intervention group or the control group, each consisting of 48 participants. Women who did not complete the baseline assessment (T1), failed to respond for two consecutive sessions or withdrew from the study for any reason were excluded from the final analysis. Ultimately, 36 women in the intervention group (75%) completed the full study

protocol, providing the necessary data for post-intervention analysis.

A pilot study was conducted among a sample of 15 pregnant women at one antenatal clinic in Damanhur City before the trial to confirm clarity, cohesiveness, and feasibility. The findings demonstrated that the ICBT program was viable and positively received, with participants indicating less fear of childbirth and enhanced self-efficacy. Minor changes were implemented in the program, such as streamlining certain cognitive restructuring activities and improving accessibility by supplying supplementary textual materials in conjunction with video information.

Eligibility criteria

The inclusion criteria for participation in this study were as follows: (1) willingness to engage in the ICBT program, (2) a fear of childbirth score between 40 and 64 on the Childbirth Attitude Questionnaire (CAQ), (3) age between 18 and 34 years, (4) gestational age of at least 28 weeks, as determined by an accurate last menstrual period, (5) a singleton pregnancy, (6) the ability to read, write, and understand the study questionnaires, (7) access to a smartphone with internet connectivity, and (8) no prior participation in antenatal interventions or educational programs.

The exclusion criteria included (1) a diagnosis of pathological anxiety or depression, (2) pregnancies complicated by significant health conditions such as hypertension, infections, diabetes, or obesity, (3) a recent history of pregnancy complications, (4) failure to complete at least two modules of the intervention program, (5) a recent history of miscarriage or neonatal loss, (6) a history of infertility, and (7) lack of reliable access to the internet.

Figure 2 presents a flow diagram illustrating the study's enrollment and participant flow. Data collection occurred at two time points: baseline (T1) and post-intervention (T2). This study protocol was registered with ClinicalTrials.gov (Identifier: NCT06640608).

Instruments

Three standardized instruments were utilized to collect data to achieve the study objectives. Trained researchers conducted face-to-face interviews with participants at baseline (pre-intervention, T1) and six weeks post-intervention (T2) during their routine antenatal follow-up visits at the outpatient clinics of the study settings. The same instruments were administered at both time points to assess changes over the course of the study.

Sociodemographic and obstetric questionnaire

A structured sociodemographic and obstetric questionnaire was developed by the researchers based on

a comprehensive literature review. This questionnaire aimed to collect essential participant information pertinent to the study. The sociodemographic section gathered data on participants' age, educational level, and employment status. The obstetric section included items on gestational age, parity, pregnancy intention (planned or unplanned), and regularity of antenatal care visits. This instrument facilitated the collection of baseline characteristics and allowed for assessing any changes in obstetric variables during the study period.

Childbirth attitude questionnaire (CAQ)

The Childbirth Attitude Questionnaire (CAQ) is a validated tool designed to assess fear of childbirth. Originally developed by Areskog, Kjessler, and Uddenberg (1981) and later adapted by Lowe (2000) [53, 54], the CAQ comprises 16 items rated on a four-point Likert scale ranging from 1 (not at all) to 4 (very much). Total scores range from 16 to 64, with higher scores indicating greater levels of fear regarding childbirth. The CAQ categorizes fear levels into four groups:

Low fear: 16–27.
Mild fear: 28–39.
Moderate fear: 40–51.
Severe fear: 52–64.

The instrument has demonstrated good internal consistency, with Cronbach's alpha of 0.83 reported by Lowe (2000) [55]. In this study, the Arabic version of the CAQ, validated by Abd El-Aziz et al. (2017) [56], was employed to ensure cultural and linguistic appropriateness for the Egyptian population. The Arabic CAQ has shown strong internal consistency in previous research. The current study demonstrated excellent reliability, with Cronbach's alpha coefficient of 0.893.

Childbirth self-efficacy inventory (CBSEI)

The Childbirth Self-Efficacy Inventory (CBSEI), developed by Lowe (1993) [57–59], is a widely used instrument that measures a woman's confidence in her ability to cope with labour and childbirth. It is grounded in Bandura's self-efficacy theory [60]. The original CBSEI consists of two subscales, efficacy and outcome expectancy, each containing items related to coping behaviours during the first and second stages of labour [61].

For this study, the researchers utilized the culturally adapted Arabic version of the CBSEI, translated and validated by Abujilban, Sinclair, and Kernohan (2012) [62]. The Arabic CBSEI is a shortened form comprising 32 items that cover the entire labor process without separating it into distinct stages. The instrument includes two parallel subscales:

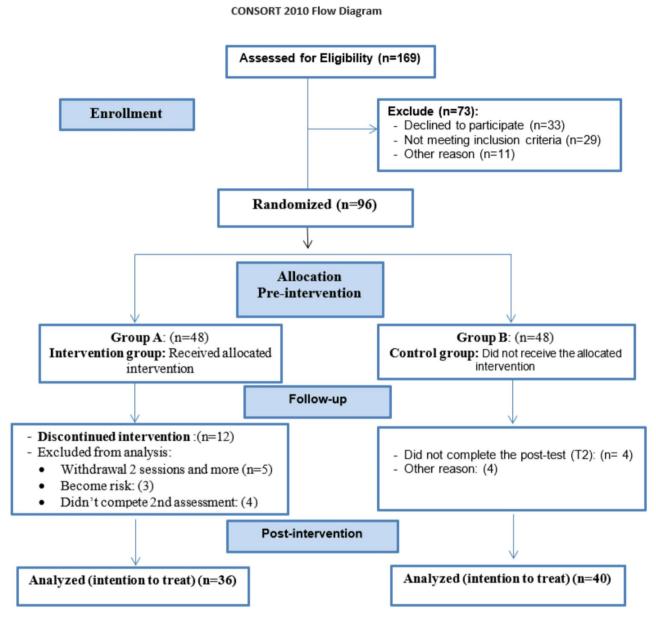


Fig. 2 Flow chart

- Efficacy Expectancy Subscale: This subscale assesses the woman's confidence in her ability to perform specific coping behaviors during childbirth.
- Outcome Expectancy Subscale: This subscale measures women's belief that performing these behaviors will lead to desired outcomes during childbirth.

Each subscale consists of 16 items, with responses rated on a 10-point Likert scale ranging from 1 (not at all confident) to 10 (completely confident). Higher scores indicate greater self-efficacy in childbirth.

The Arabic version of the CBSEI has demonstrated strong internal consistency in previous studies, with

Cronbach's alpha values of 0.86 for the outcome expectancy subscale and 0.90 for the efficacy expectancy subscale. The original authors were permitted to use the Arabic-translated CBSEI. In the current study, the CBSEI exhibited high reliability, with a Cronbach's alpha coefficient of 0.880, indicating robust internal consistency.

Data collection procedure

Data was collected at two points: baseline (T1) before the intervention commenced and post-intervention (T2) six weeks after randomization. During each assessment, participants completed the sociodemographic and obstetric questionnaire, the CAQ, and the CBSEI. The face-to-face interviews were conducted in a private setting within the

outpatient clinics to ensure confidentiality and comfort. Using the same instruments at both points allowed for evaluating changes in fear of childbirth and self-efficacy levels attributable to the intervention.

Validity and reliability

The instruments used in this study have established validity and reliability in previous research and were further validated within the context of this study. The Arabic versions of the CAQ and CBSEI were specifically chosen for their cultural relevance and linguistic appropriateness for the Egyptian population. The high Cronbach's alpha coefficients obtained in this study (0.893 for the CAQ and 0.880 for the CBSEI) indicate the instruments' excellent internal consistency and reliability, supporting their suitability for assessing the study variables.

Internet-based cognitive behavioral therapy (ICBT) program

The Internet-Based Cognitive Behavioral Therapy (ICBT) program was developed specifically for pregnant women experiencing fear of childbirth (tokophobia) and was delivered to the intervention group over six consecutive weekly modules. The program aimed to educate and support women in their late pregnancy through a structured online childbirth education curriculum. Each module was designed to build upon the previous one, fostering a supportive environment where participants could express their experiences and fears. By employing Cognitive Behavioral Therapy (CBT) techniques such as cognitive restructuring, exposure therapy, and behavioral interventions, the program sought to reduce participants' fears by helping them identify and challenge negative thoughts and emotions related to childbirth and delivery.

The ICBT program incorporated gradual exposure to childbirth-related stimuli and integrated relaxation strategies such as deep breathing, progressive muscle relaxation, and mindfulness exercises to help manage anxiety during labor. Additionally, the program provided accurate information about childbirth processes, pain management options, and strategies to enhance participants' sense of control over labor and delivery. By the end of the program, participants were expected to feel more empowered and equipped to confront their fears of childbirth with greater confidence and reduced anxiety.

Program development and validation

Two authors, specialists in psychiatric mental health nursing and midwifery nursing, designed and implemented the program. A panel of five professors specializing in obstetric and gynecological nursing and psychiatric mental health nursing thoroughly reviewed the program to ensure content validity. Based on their feedback, necessary modifications were made. The final program was culturally adapted and tailored to meet the specific needs of Egyptian pregnant women.

Program structure and content

The ICBT program consisted of six modules delivered over six weeks. Each module included audio-visual presentations, instructional videos covering scheduled topics, researchers' instructions, and homework assignments. Oral instructions and written materials were provided to clarify homework tasks. The content of each module was delivered weekly at a fixed time through a WhatsApp group specifically created for the intervention group. A reminder was sent to all participants on the day of the program, approximately three hours before the session began Table 1.

Program delivery and participant engagement

Before each module began, researchers collected reflections and feedback from the previous session to tailor the upcoming content accordingly. Participants were encouraged to engage actively, complete homework assignments, and practice the skills taught. The researchers provided weekly feedback and support to participants, promptly addressing any questions or concerns. Individual feedback was given on assignments to ensure comprehension and application of the taught skills.

To maintain adherence and program integrity, participants who did not provide feedback or complete assignments for two consecutive modules were excluded from the study. While WhatsApp was the primary communication and content delivery platform, phone calls occasionally provided additional support and feedback when necessary. This multimodal communication approach ensured that participants remained engaged and received personalized attention.

Control group

Participants in the control group received routine antenatal care without any additional intervention related to the ICBT program. They were unaware of the intervention group's activities to prevent contamination of the study results. Researchers maintained communication with the control group via a separate WhatsApp group to provide general support and address any concerns related to their pregnancy. However, they did not offer any guidance or materials from the ICBT program. Upon completion of the intervention and after the second assessment (T2), the control group was offered access to the same program content to ensure ethical considerations and provide them with the potential benefits of the intervention.

Methods of data collection

After receiving official approval from the Local Committee of Bioethics (LCBE) at the Faculty of Nursing, Damanhour

Table 1 Contents of the ICBT Program modules

Module	Title	Contents
1	Introduction and Assessment	 Introduction to the program's aim, methods, duration, frequency, and objectives of each module. Assessment of fear of childbirth: causes, manifestations, and impacts on maternal well-being and the birth process. Teaching relaxation techniques (breathing exercises).
2	Cognitive Restructuring	 Identifying negative thoughts and emotions related to childbirth. Discussing the impacts of fear of childbirth on mental well-being. Introducing the concept of cognitive distortions. Assisting participants in confronting negative thoughts about childbirth. Sharing videos of birthing experiences or virtual tours of delivery rooms. Assigning homework: maintaining a fear diary. Teaching relaxation techniques (mindfulness exercises).
3	Exposure Therapy	 Confronting participants with their fears through controlled exposure to childbirth-related stimuli (ranking fears from least to most anxiety-provoking). Sharing videos of delivery rooms and procedures carried out during delivery. Assigning homework: documenting expectations of fear and strategies to control it. Reinforcing the practice of learned relaxation techniques.
4	Psycho- educational Intervention	 Providing accurate information about childbirth and correcting misinformation. Explaining stages of labour and their manifestations. Identifying warning signs of labour. Sharing videos on preparation for delivery and the childbirth process. Assigning homework: monitoring fetal movements. Teaching relaxation techniques (progressive muscle relaxation).
5	Labor Preparation	 - Identifying labour pain and its characteristics. - Teaching effective coping strategies for labour pain using non-pharmacological methods. - Sharing videos on pushing techniques during the second stage of labour. - Assigning homework: practising coping strategies.
6	Summary and Evaluation	 Obtaining feedback on previous modules. Discussing changes in thoughts and feelings about childbirth. Reviewing information obtained during the program. Reinforcing relaxation techniques (breathing exercises, mindfulness, and other methods). Evaluating the group process. Concluding the program and addressing any remaining questions.

University, the researchers identified participants exhibiting moderate to severe fear of childbirth through initial screenings at antenatal clinics. Meetings were scheduled at follow-up clinics to assess eligibility based on the inclusion and exclusion criteria and to obtain informed consent. During these meetings, the researchers thoroughly explained the study's objectives, methodologies, session structures, and the voluntary nature of participation. Participants were assured of confidentiality and anonymity. Women who provided written informed consent (n = 96)completed the pre-intervention assessments at the clinics, including the sociodemographic and obstetric questionnaire, the CAQ, and the CBSEI. Using a computer-generated randomization sequence to ensure allocation concealment, Participants were randomly assigned to either the intervention group (n = 48) or the control group (n = 48). Randomization was essential to reduce selection bias and ensure the study's internal validity.

Data were collected at two points throughout the six-week intervention period: baseline (T1) before the intervention commenced and post-intervention (T2) six weeks after randomization. During each assessment, participants completed the same instruments to evaluate changes in fear of childbirth and self-efficacy levels

attributable to the intervention. Researchers arranged follow-up meetings at the antenatal clinics for the second assessment, ensuring consistency in data collection procedures.

Ethical considerations

The study protocol was approved by the Institutional Review Board at the Faculty of Nursing, Damanhour University (Research Code: 56-C) and registered with ClinicalTrials.gov (Identifier: NCT06640608). Prior to participant recruitment, official permissions were obtained from the directors of the relevant primary healthcare centers in Damanhour, Egypt. Participants were informed about the study's objectives, procedures, potential benefits, and their right to withdraw at any time without adverse consequences. Informed consent was obtained from all participants, with consent forms included in both the online and printed questionnaires. To ensure anonymity and privacy, each participant was assigned a unique code number in accordance with the Declaration of Helsinki [63]. Data were securely stored in password-protected electronic accounts accessible only to the research team. Results were reported in aggregate form to prevent the identification of individual

participants, and no personal identifiers were used in any reports or publications.

Statistical analysis

Data were analysed using IBM SPSS Statistics software version 27.0. The Shapiro-Wilk test was utilised to assess the normality of distribution for continuous variables. Categorical variables were summarised as frequencies and percentages, and comparisons between groups were conducted using the Chi-square or Fisher's Exact tests when appropriate. For normally distributed continuous variables, means and routine deviations were calculated, and the independent samples t-test (Student's t-test) was employed to compare the two groups. Partial eta squared (η^2) was calculated to determine the intervention's effect size on the outcome variables. Simple linear regression analysis was performed to evaluate whether the intervention program was significantly more effective than routine antenatal care in decreasing fear of childbirth and increasing self-efficacy scores. The beta coefficients (β) and their 95% confidence intervals (CIs) were reported. A p-value of less than 0.05 was considered statistically significant for all statistical tests.

Results

This section presents the findings of our randomised controlled trial evaluating the efficacy of Internet-based Cognitive Behavioral Therapy (ICBT) in reducing fear of childbirth and enhancing maternal self-efficacy among Egyptian pregnant women.

Table 2 comprehensively analyses sociodemographic and obstetric characteristics across the study groups. Chi-square tests and Student's t-tests were employed to assess group differences. Notably, no statistically significant differences were observed between the intervention and control groups in terms of age distribution (p=0.271), educational level (p=0.142), occupation (p=0.827), gestational age (p=0.089), parity (p=0.217), pregnancy planning (p=0.268), or antenatal follow-up (p=0.627).

Table 3 provides a critical comparison of childbirth fear and self-efficacy scores between the study groups. The analysis reveals several statistically significant findings. Regarding fear of childbirth, while both groups showed similar baseline scores (p = 0.713), post-intervention scores differed significantly (p < 0.001). The intervention group demonstrated a substantial reduction in fear (30.2% improvement, η^2 = 0.876), compared to negligible change in the control group. For self-efficacy, again, baseline scores were comparable (p = 0.273), but post-intervention scores showed a significant difference (p=0.011). The intervention group exhibited a marked increase in self-efficacy (16.9% improvement, η^2 = 0.600), contrasting with minimal change in the control group. Figure 3 visually represents the changes in Childbirth Fear and Self-Efficacy measures over time for both

Table 2 Analysis of sociodemographic and obstetric characteristics in the study groups (n = 96)

Socio-demographic and obstetric characteristics	All participants (n = 96)		Control (<i>n</i> = 48)		Study (n = 48)		Test of sign.	р
	No.	%	No.	%	No.	%	_	
Age (years)								
18 ≤ 25 years	37	38.5	16	33.3	21	43.8	$\chi^2 = 2.904$	$^{MC}p = 0.271$
25 ≤ 35 years	50	52.1	29	60.4	21	43.8		
≥35 years	9	9.4	3	6.3	6	12.5		
Mean ± SD	25.80±4	1.87	26.27 ± 4.05		25.33 ± 5.57		t = 0.943	0.348
Educational level								
Secondary (high school or less)	37	38.5	15	31.3	22	45.8	$\chi^2 = 2.155$	0.142
College and more	59	61.5	33	68.8	26	54.2		
Occupation								
Housewife	65	67.7	32	66.7	33	68.8	$\chi^2 = 0.048$	0.827
Employed	31	32.3	16	33.3	15	31.3		
Gestational age weeks	31.44±	3.06	32.0 ±	1.06	30.92	±2.80	t=1.718	0.089
Parity								
Nulliparous	42	43.8	18	37.5	24	50.0	$\chi^2 = 1.521$	0.217
Multiparous	54	56.3	30	62.5	24	50.0		
Planning of pregnancy								
Planned	88	91.7	46	95.8	42	87.5	$\chi^2 = 2.275$	0.268
Unplanned	8	8.3	2	4.2	6	12.5		
Antenatal follow-up								
Yes	74	77.1	38	79.2	36	75.0	$\chi^2 = 0.236$	0.627
No	22	22.9	10	20.8	12	25.0		

χ²: Ch- square test MC: Monte Carlo t: Student t-test

Table 3 Comparison between study groups' scores regarding the level of childbirth fear and self-efficacy

Variables	All participants	Control	Intervention	Test of sign.	р	
Fear of childbirth (tokophobia)	(n=96)	(n=48)	(n = 48)			
Pre						
$Mean \pm SD$	47.22 ± 3.85	47.08 ± 3.82	47.35 ± 3.35	$t_1 = 0.369$	0.713	
Post	(n = 76)	(n = 40)	(n = 36)			
Mean±SD	40.43 ± 7.84	.84 47.10±2.20 33.03:		$t_1 = 17.40^*$	< 0.001*	
Mean difference	-6.79	+0.02	-14.32			
t ₂ (p)	6.478 [*] (< 0.001 [*])	0.801 (0.428)	15.738 [*] (< 0.001 [*])			
% of improvement	14.4%	0.0%	30.2%			
η^2	0.358	0.016	0.876			
Self-Efficacy Scale	(n = 96)	(n = 48)	(n = 48)			
Pre	233.8±60.8	240.7 ± 63.0	227.0 ± 58.4	$t_1 = 1.102$	0.273	
	(n = 76)	(n=40)	(n = 36)			
Post	248.5 ± 54.9	233.5 ± 56.9	265.3 ± 48.0	$t_1 = 2.623^*$	0.011*	
Mean difference	+14.7	+7.2	+38.3			
t ₂ (p)	4.248* (< 0.001*)	1.582 (0.122)	6.506* (< 0.001*)			
% of improvement	6.3%	3.0%	16.9%			
η^2	0.200	0.060	0.600			

χ²: Chi-square test for comparing the two groups

the intervention and control groups. This graphical presentation offers an intuitive understanding of the intervention's impact and complements the statistical analyses presented in the tables.

The upper graph illustrates the trajectory of Childbirth Fear scores. At baseline (T1), both groups start at similar levels, confirming the effectiveness of randomization. However, a clear divergence is observed as we move to the post-intervention time point (T2). The intervention group shows a marked decrease in fear scores, represented by a steep downward slope. In contrast, the control group's line remains relatively flat, indicating little change over time. This visual representation clearly demonstrates the substantial impact of the Internet-based Cognitive Behavioral Therapy (ICBT) intervention in reducing fear of childbirth.

The lower graph depicts changes in Self-Efficacy scores. Again, we see comparable starting points for both groups at T1. Post-intervention, the graph reveals a notable increase in self-efficacy scores for the intervention group, illustrated by an upward trajectory. The control group, however, shows a slight downward trend, suggesting a minor decrease in self-efficacy over time. This graphical evidence supports our statistical findings, visually confirming the positive effect of the ICBT intervention on maternal self-efficacy.

The contrasting trajectories between the intervention and control groups in both graphs provide compelling visual evidence of the intervention's effectiveness. These line graphs offer an accessible means of understanding the study's key outcomes, complementing the more detailed statistical analyses presented in the tables.

Table 4 presents a two-way ANOVA model examining the effects of various sociodemographic and obstetric factors on pre-intervention fear of childbirth. The analysis revealed significant interactions between fear levels and age (F=4.095, p=0.020), education (F=6.792, p=0.011), gestational age (F=11.202, p=0.001), and parity (F=9.554, p=0.003). These findings suggest that younger age, lower educational attainment, advanced gestational age, and nulliparity are associated with higher levels of childbirth fear.

Table 5 employs simple linear regression to compare post-intervention measures between groups while controlling for potential confounders. The analysis confirms the significant impact of the intervention on both fear of childbirth (β = -0.902, p<0.001) and self-efficacy (β =0.292, p=0.011). Notably, the intervention group status explained a substantial proportion of the variance in fear of childbirth scores (R^2 = 0.813) and a smaller but significant proportion in self-efficacy scores (R^2 = 0.085). These findings, adjusted for demographic factors, reinforce the robustness of the intervention's effects and suggest its potential as a valuable tool in addressing childbirth-related psychological concerns among pregnant women.

 t_1 : Student t-test for comparing between study and control in each pre and post-intervention

 $[\]mathsf{t}_2$: Paired t-test comparing pre and post-intervention in each study and control

η²: Partial Eta Squire

^{*} Statistically significant p-value at ≤ 0.05

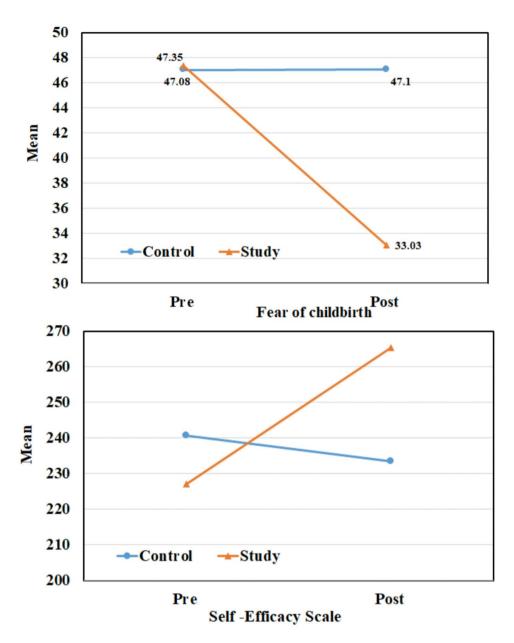


Fig. 3 Line graphs comparing measures in the intervention and control groups regarding Childbirth fear and self-efficacy measures

Discussion

In this study, we evaluated the effectiveness of an Internet-based Cognitive Behavioral Therapy (ICBT) intervention for women experiencing fear of childbirth, focusing on reducing fear symptoms and enhancing self-efficacy scores. This is one of few Arabic online studies focusing on evaluating the effectiveness and feasibility of ICBT in managing Childbirth-related fears Al-Jahdali et al. (2021)& Al-Amin (2022) [64, 65]. The high levels of childbirth fear in this sample at pretest reflect the inability of the current antenatal care to meet the needs of pregnant women. Significant improvements in fear of childbirth and self-efficacy were observed after the intervention. These results may be attributed to the easy

accessibility and convenience of internet platforms that facilitate adherence to the program, helping pregnant women through utilizing cognitive restructuring to identify their negative thoughts related to their own perceptions of the childbirth process, including pain and major complications to themselves and to their babies [41, 44, 66–68]. Discussing these critical points openly can foster a more positive perspective on the childbirth experience [69]. Additionally, allowing women to engage with therapeutic content at their own pace and the privacy afforded can encourage more open discussions about fears and concerns, in addition to the previous technique. Furthermore, behavior intervention techniques that teach relaxation can also help reduce the stress that occurs in

Table 4 Two-way ANOVA model for the effect of different sociodemographic and obstetric factors

Fear of childbirth /Pre	$Mean \pm SD$	F	p
Interaction x Age			
18 ≤ 25 years	49.11 ± 0.32		
25 ≤ 35 years	46.96 ± 3.62	4.095*	0.020*
≥35 years	42.60 ± 3.85		
Interaction x Education			
Secondary (high school or less)	49.09 ± 0.29		
College and more	45.88 ± 4.02	6.792*	0.011*
Interaction x Occupation			
Housewife	47.30 ± 3.32		
Employed	47.47 ± 3.35	0.168	0.683
Interaction x Gestational age			
< 30	45.76 ± 4.05		
≥30	49.09 ± 0.29	11.202*	0.001*
Interaction x Parity			
Nulliparous	49.07 ± 0.26		
Multiparous	44.74 ± 4.16	9.554*	0.003*
Interaction x Antenatal follow-up			
Yes	47.44 ± 3.29		
No	47.08 ± 3.35	0.083	0.774

F, p: f and p values for the model

response to the childbirth process [70]. Previous studies have highlighted ICBT programs as promising alternatives for managing childbirth fear by facilitating women's engagement in the therapeutic content [46, 71–73]. The program demonstrates the principles of cognitive restructuring could improve mental well-being during pregnancy [47, 63]. Therefore, the need for more accessible practical programs during late pregnancy is vital for helping women approach childbirth fear positively.

Our study's findings indicated that participants who received ICBT intervention exhibited improved self-efficacy than those who received routine antenatal care. This improvement can be attributed to the practical nature of the instruction, which went beyond theoretical content where the researcher provided verbal and written instructions and employed more practical methods such as role play and videos to help pregnant women become familiar with the delivery process and to teach practical skills to minimize the stress and fear related to childbirth and adapt more effectively that potentiate their self-efficacy in managing childbirth related fears. Another reason is that the flexibility of an ICBT allows the women to return to previous modules [74–77]. The present study's results are in line with findings by Loughnan et al. (2018), Duan et al. (2022) & Mamukashvili-Delau et al. (2022), Who reported significant improvements in pregnant confidence in their ability to handle labor and delivery after completing the ICBT modules as the structured online format of ICBT allows skill-building, and enabling women to develop practical strategies for dealing with stress and fear [78-80]. Overall, these results suggest that ICBT can be a powerful tool for empowering expectant mothers during this pivotal time.

The present results indicate some sociodemographic factors, such as younger age and lower educational levels, can significantly positively impact childbirth-related fear. this may be due to a lack of experience with young age and limited available resources about childbirth that increase fear about childbirth. These results are on the same track with others Araji, et al. (2020), Loughnan et al. (2018) [78, 81], who reported that younger pregnant and who had limited education often experience heightened anxiety due to concerns about their health and

Table 5 Comparison of the intervention and control group measures using simple linear regression

Post	Factor	β	t	р	95% CI of B		R ²	F	р
					LL	UL	_		
Fear of childbirth (tokophobia)	Intervention	-0.902	-17.962*	< 0.001*	-15.633	-12.511	0.813	322.640*	< 0.001*
	Age	0.024	0.209	0.835	-0.382	0.472	0.001	0.044	0.835
	Education	0.114	0.991	0.325	-1.728	5.146	0.013	0.982	0.325
	Gestational age	0.220	1.938	0.056	-0.016	1.144	0.048	3.757	0.056
	Parity	-0.226	-1.985	0.052	-3.884	0.008	0.051	3.940	0.052
Self-Efficacy Scale	Intervention	0.292	2.623*	0.011*	7.660	56.057	0.085	6.881*	0.011*
	Age	-0.134	-1.163	0.249	-37.353	9.819	0.018	1.353	0.249
	Education	0.037	0.321	0.749	-20.302	28.107	0.001	0.103	0.749
	Gestational age	0.012	0.102	0.919	-3.949	4.374	0.001	0.010	0.919
	Parity	0.054	0.463	0.645	-10.821	17.361	0.003	0.214	0.645

F, p: f and p values for the model

^{*:} Statistically significant at $p \le 0.05$

R²: Coefficient of determination

Beta: Standardized Coefficients

LL: Lower limit UL: Upper Limit

t: t-test of significance

^{*:} Statistically significant at $p \le 0.05$

potential complications during pregnancy and delivery. Also, younger pregnant women are more susceptible to societal pressures and personal insecurities, which can exacerbate their fears about childbirth. Moreover, pregnant who are experiencing childbirth for the first time frequently report greater fear and uncertainty, as they lack prior experience to draw upon [82, 83]. Additionally, as pregnancy progresses to a later gestational age, concerns about potential complications and the physical experience of childbirth can intensify, further exacerbating fear [82, 83]. These highlight the need for tailored interventions based on significant factors to support those with such risk demographic variables. Addressing these fears through education and psychological support could be crucial in improving maternal mental health and outcomes during childbirth.

Strengths and limitations

This study has several strengths; This is one of few ICBT programs for women with a fear of childbirth, especially in the Arab world; the randomized controlled design, the sample size, and the equivalence between the groups at baseline are important factors for the validity. An important advantage is the internet format, which ensures a certain degree of anonymity and privacy and reduces the barriers to help-seeking and cost-effectiveness.

This study also has limitations

- 1. We did not screen for anxiety or depression through assessment tools as we depend on participants' subjective data, thus the generalizability is limited.
- 2. another factor may interfere with participants' engagement in the program as accessibility to the internet or interest in technology can have restricted the range of women who participated in our trial.
- 3. The short duration of an online program may not have been enough to bring about significant improvements in self-efficacy.
- 4. The study did not assess participant's satisfaction with the program intervention but relied on the participants' responses and feedback.

Conclusions

There is an urgent need for practical, accessible, and effective Internet-based CBT interventions to help manage childbirth-related fears. This ICBT program has been shown to directly improve scores related to childbirth fears and self-efficacy in pregnant individuals experiencing these concerns, all without requiring extra services, payment fees, or additional healthcare resources.

Practical recommendations

- The current study provides evidence on the efficacy and cost-effectiveness of Internet-based cognitive behavioral intervention and its recommendation as a practical and accessible intervention to reduce fear of childbirth women. Our findings recommended the following:
- 2. To enhance the program's benefits, healthcare providers, including midwifery Nurses, should utilise and implement the program in antenatal clinics during follow-up, particularly for high-risk women.
- 3. Further follow-up is necessary to evaluate the program's long-term effects.
- 4. Systematic reviews and meta-analyses are required to assess the effectiveness of online cognitive behavioral interventions.
- 5. To evaluate the effectiveness of such ICBT interventions, it would have been better to compare the Internet-based CBT group with face-to-face groups.
- 6. This study could be implemented in clinical practice and hopefully.

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Author contributions

O.M.E.R. contributed to the conception and design of the study, performed data analysis, and drafted the manuscript. A.H.H., N.E.K., and A.A. were responsible for data collection and contributed to data interpretation. N.B.E. and E.M.A. also contributed to data collection and manuscript revision. M.S. supported data collection and interpretation. A.M.A. and N.I.M.B. provided critical revisions, contributed to the study design, and assisted in data analysis. All authors reviewed and approved the final manuscript.

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Data availability

The datasets generated and analysed during the current study are available from the corresponding author upon reasonable request.

Declarations

Institutional Review Board Statement

The study was conducted following approval from the Ethical Committee of the Faculty of Nursing, Damanhour University (research code: 56-C) and registered with ClinicalTrials.gov (Identifier: NCT 06640608), with the registration date of October 15, 2024.

Informed consent

Written informed consent was obtained from all participants prior to their inclusion in the study, ensuring their awareness of the study's aims, procedures, and their right to withdraw at any time.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Clinical Trial Registration

The study was registered on ClinicalTrials.gov under the identifier (NCT06640608) on October 15, 2024.

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