Efficacy of supervised pelvic floor muscle training with a home-based biofeedback device for urinary incontinence in postpartum women: protocol for a multicentre randomised controlled trial

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ABSTRACT

Introduction Supervised pelvic floor muscle training (PFMT) of at least 3 months duration has been strongly recommended as a first-line treatment for women with stress urinary incontinence (SUI) or SUI-predominant mixed urinary incontinence (MUI), including elderly and postnatal women. However, for the treatment of SUI and MUI in postpartum women, it is currently uncertain whether supervised PFMT combined with a biofeedback device is superior to PFMT alone. Despite some supportive results, more reliable evidence is lacking.

Methods and analysis The study is designed as a multicentre assessor-blinded parallel-group randomised controlled trial comparing the efficacy of PFMT with a home-based pressure-mediated biofeedback device (intervention group) and that of at-home PFMT alone (control group) for women with new-onset SUI or SUI-predominant MUI after delivery. Five hundred eligible women from the obstetric outpatient clinics of five tertiary hospitals will be randomly allocated (1:1) and evaluated with repeated questionnaires, physical examinations and pelvic floor assessments at baseline (pretreatment), 3 months, 6 months and 12 months (posttreatment) during the study period. Both groups will be instructed to follow the same training protocol over 3-month supervision after randomisation. The use of a biofeedback device with a self-assessment function will be added to the PFMT regime for patients in the intervention group. The primary outcome is the self-reported severity of urinary incontinence assessed through the short form of the International Consultation on Incontinence Questionnaire—Urinary Incontinence. Secondary outcomes include pelvic muscle support and strength, symptoms of pelvic organ prolapse, quality of life, sexual function, self-efficacy and adherence.

Ethics and dissemination Ethical approval has been received from the Peking Union Medical College Hospital ethics committee (JS-3192D). All results from the study will be submitted to international journals and international conferences.

Trial registration number NCT05115864.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The design of our study is based on a relatively large sample size and a long-term follow-up after intervention conducted in multiple centres.
⇒ The key population of interest in our study is postpartum women, who are a major population experiencing stress urinary incontinence, as there is a lack of attention and clinical trials exploring additional approaches to enhancing efficacy.
⇒ To reduce bias, both groups follow the same programme except for the use of a biofeedback device by unifying the training protocols and the frequency of supervisor contacts; moreover, the assessor is blinded to the group allocation and will remain so during the study period.
⇒ An application that allows patients to use just one application for everything during the study period including answering the questionnaires and visualising the real-time progress of pelvic floor muscle contraction has been developed.
⇒ The primary limitation is that the intervention can only be blinded to assessors but not to participants and supervising physicians. Another limitation is the Chinese version of Incontinence Quality of Life Instrument adopted has not been validated.

INTRODUCTION

Stress urinary incontinence (SUI), which is the most common type of pelvic floor dysfunction, is a significant medical problem that 25%–45% of women will experience in their lifetime, especially postnatal and elderly women.1 This is mainly due to the damage caused by stretching and tearing of the pelvic floor muscles (PFMs) during pregnancy and childbirth and hormonal changes occurring during pregnancy to soften PFMs to prepare for delivery.2 3 The estimated prevalence of urinary incontinence (UI) during late...
pregnancy and postpartum is 17%–67% and 6.8%–36%, respectively, according to the previous studies depending on various measurements including cough stress test, urodynamics and patient-reported questionnaires.\textsuperscript{4,6} The prevalence also varies among counties, 24.3% and 26.7% of women in late pregnancy and 12.6% and 6.8% of women at 6 months postpartum reported UI in Italy and China, respectively.\textsuperscript{7,8} SUI not only has a significant effect on the quality of life but also creates severe socioeconomic burdens, with healthcare costs reaching from £80 million to £100 million annually according to the UK National Health Service.\textsuperscript{9}

Supervised PFM training (PFMT) of at least 3 months duration has been strongly recommended in the international guidelines as a first-line treatment for women with SUI or SUI-predominant mixed urinary incontinence (MUI), including elderly and postnatal women (Level I evidence).\textsuperscript{1,10–12} The efficacy of PFMT lies in the fact that urethral support can be enhanced by the elevation of pelvic floor structures via PFM contractions, which increase the thickness and shorten the fibres of PFMs to close the levator hiatus and lift the bladder neck.\textsuperscript{13–14}

Regarding the prevention and treatment of UI in postpartum women, several studies have demonstrated that women receiving PFMT are less likely to report UI after delivery than women receiving no treatment (moderate-quality evidence).\textsuperscript{15–18} Previous systematic reviews have also demonstrated that PFMT is effective in improving UI in pregnant and postpartum women.\textsuperscript{15,19,20}

Therefore, after the introduction of PFMT into clinical practice, physicians began to wonder whether it was possible to develop an adjunctive method that would provide additional benefits over PFMT alone. To date, a large number of combinations have been proposed, including biofeedback, electrical stimulation, vaginal cones and a bladder diary; however, none of these methods has gained widespread acceptance thus far. Among all these approaches, biofeedback is the most likely to be recognised as effective. The European Association of Urology guidelines point out that there are greater benefits with the addition of biofeedback and supervised high-intensity regimes, including increased treatment efficacy, enhanced patient convenience and compliance and reduced treatment costs in women with SUI (Grade A).\textsuperscript{21}

Regarding the treatment efficacy of SUI, some studies have proved that combining PFMT with biofeedback might be more effective than engaging in PFMT alone.\textsuperscript{7} A randomised controlled trial compared home-based biofeedback added to home PFMT with PFMT alone among 72 women with SUI and demonstrated that the probability of recovery is three times higher in patients receiving biofeedback than in those having only PFMT after 3 months of supervised treatment.\textsuperscript{22} Several reviews found that patients accepting PFMT with device-mediated biofeedback were more likely than patients receiving PFMT alone to report cured or improved UI.\textsuperscript{23}

Regarding patient convenience and the healthcare cost of SUI, some studies have reported that biofeedback is useful in promoting correct contraction control and improving motivation and adherence by providing visualisation of their PFM activity so that women can be aware of how to contract their PFMs during training. In addition, according to the guideline recommendations, innovative methods such as home therapy may have offered more opportunities allowing PFMT to be performed during the COVID-19 pandemic for avoiding face-to-face interventions or being interrupted by unpredictable events such as quarantines.\textsuperscript{24–25} The US Food and Drug Administration has approved the over-the-counter sale of many personal biofeedback devices for the treatment of SUI.\textsuperscript{26}

Overall, some results support the use of home-based biofeedback devices for the treatment of SUI; however, high-quality evidence still remains scarce to prove whether supervised PFMT combined with home-based biofeedback devices is superior to supervised PFMT alone for the treatment of SUI or SUI-predominant MUI, especially among postpartum women. The available studies are not of high quality mainly due to several reasons: (1) training protocols conducted in the intervention and control groups were not unified or lacked intensity; (2) the same assessor did not remain throughout the study period, or the assessor followed a different protocol of measurements and (3) the sample was not large enough or lacked a long follow-up.

Most importantly, postpartum women who are a major group experiencing SUI were not given adequate attention and so far the efficacy of biofeedback in enhancing the benefits of PFMT is still lack of evidence. Therefore, it is important to explore an additional approach based on the existing therapeutic option (supervised PFMT alone) to improve the efficacy of treatment for SUI. Therefore, we designed a multicentre assessor-blinded randomised controlled trial focused on women who reported SUI after delivery for the first time in their life. The aim of this study is to determine whether a home PFMT programme with a home-based pressure-mediated biofeedback device is superior to a home PFMT programme alone after 3 months of supervised training. Furthermore, the rigour of the research will be enhanced and optimised in several ways as follows. The details about the PFMT programme and regular supervisions will be provided to ensure that both groups conduct the same PFMT programme (under supervision) except for the use of a biofeedback device, avoiding either group receiving a longer treatment time or more therapist contacts. Moreover, we will focus on postpartum women by using a large study population and evaluating several secondary outcomes, such as the symptoms of pelvic organ prolapse (POP), life quality, sexual function, self-efficacy and adherence. Finally, the biofeedback device used in our study has been optimised by adding a function for the self-assessment of PFM strength at home.
METHODS AND ANALYSIS

Study design

The study is designed as a multicentre assessor-blinded parallel-group randomised controlled trial, comparing PFMT with a home-based pressure-mediated biofeedback device (intervention group) and PFMT at home (control group) for women with new-onset SUI or SUI-predominant MUI 6–12 weeks postpartum, after 3 months of supervised training. The time schedule and the process flow are shown in online supplemental table 1 and figure 1. Version 1 of the protocol was completed on 20 September 2021. Patient recruitment has been conducted in five tertiary hospitals since March 2022 and is expected to last for up to 24 months, and each patient will be followed for 12 months after randomisation. The end of the study is defined as the last follow-up of the last enrolled patient and is expected to be completed in March 2025. This study protocol is based on the Standard Protocol Items: Recommendations for Interventional Trials checklist.

Patient selection and recruitment

Since March 2022, women who present for regular postpartum clinic visits at the five participating tertiary hospitals and report new-onset SUI or SUI-predominant MUI within 3 months after delivery will be instructed on the project. Afterwards, the well-trained physicians in each participating centre will screen the potentially eligible patients. Patients who meet all the criteria and express an interest in participating will be recruited. After participant eligibility is confirmed and consent obtained, the site physicians will complete the randomisation by entering the patient’s name, date of birth, phone number and picture of the consent form into the computer-generated randomisation programme in real time. The allocation status will not be concealed from nonblinded physicians, who will perform the recruitment, supervision and follow-up or from the patients but will be concealed from the assessment physicians. The inclusion and exclusion criteria are as follows.

Inclusion criteria

► 6 weeks after delivery < 3 months postpartum.
► Clinically diagnosed SUI or MUI as the primary problem. We will consider SUI and MUI following the definition recognised by international guidelines.
► Women aged 18 years or older.

Exclusion criteria

► Urgency UI alone.
► POP Quantification (POP-Q) stage ≥2.
► Third-degree and fourth-degree perineal tears.
► Presence of diastasis recti abdominis and chronic pelvic pain as the primary problem needing treatment.
► A history of SUI before pregnancy.
► Previous pelvic surgery.
► Malignant pelvic cancer.
► Urogenital infections.
► Receipt of formal instruction on PFMT in the past 5 years.
► Unsuitability to participate because of significant diseases.
► Others: inability to contract the PFMs on digital examination when requested; inability to use the device in the vagina.

Randomisation and masking

After evaluation of the inclusion criteria and assessment at baseline, patients will be randomised into an intervention group and a control group based on a computer-generated randomisation programme with an allocation ratio of 1:1. The result of the group allocation cannot be masked to the patients and physicians who are responsible for delivering the intervention and follow-up. According to the study design, the patients and the physicians who take charge of recruitment, supervision and follow-up will not be blinded to the study groups. However, the physicians performing the assessments and data analysis will be blinded to the allocation status. Meanwhile, patients will be requested not to discuss their study group status with the physicians performing the assessments.

Data collection

The demographics and health information of the patients will be collected by the self-designed electronic questionnaire via the PFMT study app at baseline and will include age, height, weight, study centre, weight gain during pregnancy, menstruation, feeding patterns, occupation type and position, educational level, toileting position, smoking, family history, sexual activity, labour and...
physical activity and medical history. Obstetrical data, including the delivery date, gravidity and parity, delivery mode and newborn weight, will be collected from the electronic medical records. Both groups will be assessed by repeated questionnaires, physical examination and manometry at baseline (pretest), 3 months, 6 months and 12 months (postintervention). The validated questionnaires used to evaluate the outcomes will be completed by the patients via the PFMT study app each time before the assessment is performed. Physical examination and manometry will be performed by the same assessment physician at each participating centre who is blinded to the allocation status. The patients’ adherence to and compliance with treatment will be subjectively recorded by a self-reported training diary via the PFMT study app and objectively recorded by the biofeedback device in the intervention group. In the control group, the adherence and compliance will be simply recorded by a self-reported training diary via the PFMT study app.

**Intervention**

We will ensure that all patients receive identical therapy, with the exception of the inclusion of pressure-mediated biofeedback. Each patient will be determined to be capable of contracting the PFMs correctly before leaving by being taught how to contract the PFMs through vaginal palpation and manometers at baseline. After randomisation, both groups will be supervised in downloading the PFMT study app designed to guide patients through the study. The PFMT study app will provide a different operation interface and function according to the allocation status. Moreover, both groups will receive a one-page handout with the details of the training protocol, while the intervention group will receive a personal home-based biofeedback device (XFT-0010CK) and an operation video. The supervision physician will ensure that the intervention group can connect the vaginal biofeedback device to the PFMT study app using Bluetooth before leaving.

Both study groups will be instructed to follow the same training protocol during the first 3 months after randomisation. The training protocol will be provided in the PFMT study app. Both groups will be asked to download the app and use it to upload the exercise diary via the PFMT study app according to the completion of the daily training. During the intervention, the supervising physician will telephone each patient in both groups, asking questions about the performance of PFMT once every 3 weeks to provide motivation and guidance. If patients experience any possible adverse events during the intervention, such as vaginitis due to the use of the intravaginal air-filled probe, they will be asked to report them at any time to the supervising physician, who will report to the study director to decide on a management plan. Training meetings will be conducted during the trial to ensure that all physicians are maintaining the protocols.

**Training protocol**

One reason why the results of previous studies were not convincing enough was that the PFMT programme was not properly designed or the intensity of the PFMT regime was not sufficient. According to the 2019 National Institute for Health and Care Excellence (NICE) guidelines on the management of UI and POP in women, PFMT programmes should comprise at least eight contractions performed three times per day. An intensive training protocol was proposed by some studies, consisting of three sets of 10 contractions at maximum intensity holding for 6 s each, three or four times a week.

Both study groups will be instructed to follow the same training protocol during the first 3 months after randomisation. The protocol includes the performance of three sets of fast and slow contractions completed per day in the supine position. Each set lasts for 6 min and comprises three replicates. Each replicate consists of eight maximal contractions (held for 6 s with a 6 s rest) followed by four fast contractions (held for 6 s with a 6 s rest) and a 30 s rest between each replicate.

**Study device**

The study device adopted in our study was designed and developed by the principal investigators of this study and Shenzhen XFT Medical Limited in September 2021 for scientific research use only. The wearable PFMT study device named XFT-0010CK is a digital device with an intravaginal insert and a battery pack. The device has a screen that is able to show the real-time value of the vaginal resting pressure (VRP) and voluntary contraction pressure in units of mm Hg. The intravaginal insert is a vaginal air-filled probe with the gas filled automatically when it starts to work. The two parts are combined with a thin air tube. The whole device is connected to the PFMT study app by Bluetooth to record the progress of and compliance with PFMT. There are two modes of the device: assessment and training modes. In regard to the assessment mode, the device is able to assess the PFM strength by the patients themselves following the instructions. The training mode is the significant mode to guide patients to complete PFMT by following the training protocol and visualising the real-time progress of PFM contraction via the PFMT study app. The biofeedback is provided according to the pressure collected by the vaginal air-filled probe during training.

**APP**

Patients in both groups will be instructed to download and install an app named the PFMT study app from the App Store, which is available for both Android and iOS smartphones and was developed by our research group in collaboration with software engineers based on the study protocol to guide both groups through the study as shown...
in Figure 2. In both groups, patients can complete the questionnaires via the app and receive a reminder within 1 week before the indicated time. Additionally, the app will send daily push reminders to both groups to remind them to complete daily PFMT. Both groups can upload the exercise diaries via the app. The app will also provide a different operation interface and function according to the allocation status. The study device connects to the PFMT study app using Bluetooth. In the intervention group, the app can support the performance of the PFM contraction by providing visual biofeedback on the PFM contraction over time while storing the duration of, frequency of and compliance with training. The control group will use the same training video three times a day.

**Outcome measures**

**Primary outcome measure**

The primary outcome will be evaluated by the International Consultation on Incontinence Questionnaire-Urinary Incontinence short form (ICIQ-UI SF), a patient-reported outcome measure for the severity of UI. The questionnaire will be administered in the Chinese and the Chinese version has been validated. It contains four items including urine leakage (score of 0=never to 5=always), amount of urine leakage (scores of 0, 2, 4 6 for increasing amounts per episode), impact of the urine leakage on life (score of 0=not at all to 10=a great deal) and types of leakage symptoms experienced in the previous 4 weeks. The ICIQ-UI SF score is the sum of the first three items ranging from 0 to 21 divided into mild (0–7), moderate (8–13) and severe (14–21). Higher scores reflect greater severity.

**Secondary outcome measures**

**POP stage**

The POP stage will be evaluated by the POP-Q system. The POP-Q approach will be used to measure the positions of vaginal structures relative to the hymenal ring. The outcomes will be recorded as Aa, Ba (points of the anterior vaginal wall); Ap, Bp (point A of the posterior vaginal wall); C, D (points of the cervix); gh (genital hiatus); pb (perineal body) and tvl (total vaginal length).

**PFM strength**

The PFM strength will be evaluated by subjective (vaginal palpation) and objective (manometer) measurements. During the assessments, each participant will be examined in the lithotomy position with an empty bladder and the head of the bed inclined at a 30° angle. The subjective PFM strength will be measured by digital vaginal palpation based on the modified Oxford grading scale. Patients will be asked to perform a maximum contraction of the muscles to squeeze and lift against the resistance provided by the assessors’ fingers in the vagina. The subjective PFM strength will be classified within the range of Grades 0–5, with higher grades reflecting better strength (0 (no contraction), 1 (flicker contraction), 2 (weak contraction), 3 (moderate contraction), 4 (good contraction) and 5 (strong contraction)).

The objective PFM strength will be defined as the maximum voluntary contraction pressure (MVCP), which is referred to as the force-generating capacity of a muscle and measured through an intra-vaginal manometer (a vaginal balloon probe filled with 20 mL gas) connected to a PHENIX USB 8 neuromuscular stimulation therapy system, which is equal to a high-precision...
pressure transducer (Electronic Concept Lignon Innovation, Montpellier, France). MVCP will be calculated as the difference between the VRP and its peak pressure during a maximum voluntary contraction. The patients will be asked to perform maximum contractions of the PFMs three times without using the abdominal, gluteal or hip adductor muscles during the contractions. Each contraction will have an interval of 15 s. The outcome will be recorded as the average of three measurements. Higher pressure is related to greater strength.

**POP severity**
The severity of the symptoms of POP will be evaluated by the POP Symptom Score questionnaire, which is a validated Chinese version that is patient-completed with seven items addressing the frequency of prolapse symptoms in the previous 4 weeks. Each item is scored from 0 (never) to 4 (all of the time), with a total score ranging from 0 to 28. Higher scores reflect greater severity.

**Quality of life**
Quality of life will be evaluated by the Chinese version of Incontinence Quality of Life Instrument with 22 items. Its Chinese version has not been validated. The instrument has three subscales: (1) avoidance and limiting behaviour, (2) psychosocial impacts and (3) social embarrassment. All items are evaluated using a 5-point Likert-type scale. The scores will be summed and transformed to a 0–100 scale. Higher scores represent better quality of life.

**Sex function**
The outcome of sex symptoms and function will be evaluated by the patient-completed Short-form Prolapse Incontinence Sexual Questionnaire Incontinence which is a Chinese version and validated, ranging from 0 to 48, with higher scores indicating greater sexual dysfunction.

**Broome Pelvic Muscle Self-efficacy Scale**
The questionnaire employed in our study to evaluate the outcomes of self-efficacy is reliable and validated. We will use a Chinese version with a 23-item rating scale consisting of two domains: efficacy expectations and outcome expectations. In the efficacy expectations domain, participants will demonstrate how confident they are in performing PFMT. In the outcome expectations domain, participants will indicate their level of confidence that the training will prevent unwanted urine leakage. The score ranges from 0 to 100. The higher the score is, the greater the self-efficacy perceived by the participant.

**Subjective treatment success**
Furthermore, patients’ perceptions of their urine leakage will also be measured through the Patient Global Impression of Improvement at 3, 6, 9 and 12 weeks during 3-month intervention. It will be recorded by the supervising physician during telephone calls with their patients every 3 weeks at 3, 6, 9 and 12 weeks during 3-month intervention. Answers to the question ‘Which best describes your urinary symptoms now, compared with how they were before this study’ are evaluated on a 7-point scale ranging from 1=Very much better to 7=Very much worse. Only answers affirming a score of 1 (very much better) or 2 (much better) will be considered to indicate improvement.

**Patient adherence to treatment**
There is no universally accepted standard for adherence. In our study, patients’ adherence to treatment will be determined as the frequency of exercises anticipated for 3 months of supervised treatment, which will be subjectively self-reported and objectively device-recorded. Patients’ overall adherence will be categorised as follows: ≤50%=low adherence; 50%–75%=medium adherence and ≥75%=high adherence.

**Statistical methods**

**Sample size**
The primary outcome of this study is the ICIQ-UI SF score. An ICIQ-UI SF minimal clinically important difference of 2.5 points was reported by Nyström E in 2015. We referred to two RCT studies reporting ICIQ-UI SF data as the primary outcome for women with SUI with 5-month and 6-month follow-ups indicated an assumed SD of 5. Another study determined an SD of 10 because they expected that the SD at the 24-month time point could possibly be as high as 10. According to our study design, it would be reasonable for us to expect an SD of 8.1 at the 12-month time point. On this basis, the sample-size calculation in our study is expected to be based on a significant difference of 2.5 points in ICIQ-UI SF scores (SD of 8.1) as the primary outcome between the groups. A sample size of 222 participants per group will detect this difference calculated through PASS V.15, with a power of 0.9 and a two-sided significance level of 0.05. Thus, a total of 500 women will be recruited (250 women per group), allowing for approximately 10% loss to follow-up during the 12-month period.

**Statistical analysis**
The data will be analysed by SPSS V.23.0 (IBM). Background and obstetric variables will be presented as the means±SDs or absolute numbers and relative frequencies with percentages (n, %). Analysis of variance (ANOVA) will be used to analyse the differences between groups at baseline (pretest), 3 months, 6 months and 12 months (postintervention). Student’s t-test will be used for analyses within the groups throughout the time-treatment. The difference in the ICIQ-UI SF scores (primary outcome) between the intervention and the control group will be analysed by using generalised linear regression models. Secondary outcomes will be analysed in a similar manner using an appropriate generalised linear model. The relationship between self-reported adherence and device-reported adherence will be assessed using a scatter plot. Subgroup analyses by type of incontinence (SUI or MUI), participant age (<35/≥35 years), parity and baseline UI
Data management

The data management system adopted in this study includes the following: a patient side for providing PFMT tasks to patients and collecting questionnaire results, side effects and PFMT data; a physician side for monitoring and managing the PFMT progress of patients and a hospital side for managing the operation process and results of the physician side and patient side within each hospital. The data management system in this study is based on the storage of the MySQL database, and the data in the management system are stored at multiple levels in the form of local cache, Redis cache and cloud storage. Senior data management staff will consistently and recurrently review data submitted into the study database for completeness, for omissions and for values needing further clarification using computerised and manual techniques. The presentation type used to publish the study data will not include participant names, pictures, personal information or any other information that could reveal their identity. This trial will be also audited by ethics committee.

Patient and public involvement

Patients and the public were not involved in the process of the study.

Ethics and dissemination

The study protocol, the informed consent form and relevant supporting information have been approved by the Peking Union Medical College Hospital ethics committee (JS-3192D, 10/26/2021). The ethics committee annually selects some studies for auditing. The study is registered on the ClinicalTrials.gov Protocol Registration and Results System (https://register.clinicaltrials.gov, registration number: NCT05115864) and Chinese Clinical Trial Registry (http://www.chictr.org.cn, registration number: ChiCTR2100052556), and all participants will sign written informed consent before data collection. All results from the study will be submitted to relevant scientific journals and international conferences. The patients can inquire about our findings after the study completion.

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Contributors

ZS will direct the whole study and ensure the execution and completion of the protocol. ZS and XW conceived and designed the study protocol. TX and GF participated to refine the details of the study design. GF trained all involved assessors in the study. TX contributed to the statistical methodology within the protocol. The study protocol was written by XW and revised by ZS. All authors read and approved the final manuscript.

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Competing interests

None declared.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication

Consent obtained directly from patient(s).

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Supplemental material

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