

Instruction for use





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Sword Bloom

Product Version: 7

Please note version number is equivalent of batch number

Sword Bloom

Sword Bloom is a medical device software (MDSW) intended to guide individuals through an exercise program directed at pelvic floor muscles and to enable pelvic health specialists to design, monitor and adjust the exercise program based on the individual's needs and progress.

INSTRUCTIONS FOR USE

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Information for Patients

Intended Use

Sword Bloom is a medical device software (MDSW) intended to guide individuals through an exercise program directed at pelvic floor muscles and to enable pelvic health specialists to design, monitor and adjust the exercise program based on the individual's needs and progress.

Note: The terminology patient/member/user is used interchangeably within this document. Likewise, the terms Pelvic Health Specialist (PHS) and Women's Health Specialist (WHS) are used interchangeably.

Intended Users

Sword Bloom is intended to be used by individuals with vaginal anatomy above the age of 18, to restore or improve movement, function and muscle strength of the pelvic floor.

It can be used both by individuals who have been recommended a course of exercise by a suitably qualified professional with experience in pelvic physical therapy but also by individuals who have not been affected by specific injury or disability related to pelvic floor issues.

Both the Sword Health App and the Bloom Pod are intended to be used by lay persons in the home (or similar) environment with sufficient room to perform the exercises. No specific education or training prior to using the device is required.

Indications for Use

Sword Bloom is primarily used to restore movement, function and muscle strength of the pelvic floor. Sword Bloom can also be used outside of its medical purpose by healthy individuals who have not been affected by injury, illness or disability for general health and wellbeing purposes, to work on improving the function of their pelvic floor.

Sword Bloom is comprised of the following:

- Sword Health App - A mobile application used by the member to receive instructions, record exercises being performed, and receive feedback from both the mobile application itself and their pelvic health specialist remotely;

- Clinical Portal - A web-based portal that the member's pelvic health specialist uses to monitor the member's performance and provide feedback.

Sword Bloom has the following accessory and component, which are supplied together in the Bloom System kit:

- An intravaginal pelvic device (Bloom Pod), used to exercise and track pelvic floor muscle movement and tone. The values collected by the device are sent to the app to allow for real-time feedback on performance;
- An optional water-based lubricant that is supplied to facilitate the insertion of the intravaginal pelvic device.

Sword Bloom is also supplied with a pod case, which is a washable fabric bag used for the storing of the Bloom Pod after cleaning.

Sword Bloom can be used without the intravaginal pelvic device through no-pod sessions. Bloom No-Pod sessions offer a way for members to access the pelvic program using only a mobile device without the pod. These sessions are integrated in the Sword Health App and contain exercises that align closely with the pod program. The option to complete no-pod sessions allows members to continue progressing through the Bloom program and maintain consistency even when without the use of the Bloom Pod.

Contraindications

Sword Bloom is not designed to be used by members presenting with any of the following conditions:

- Symptoms/signs compatible with active pelvic infection.
- Symptoms/signs compatible with acute and serious underlying medical conditions (neurological, cardiac, respiratory, gastrointestinal, genitourinary, metabolic or other) precluding participation in an exercise program.
- Respiratory, cardiovascular or metabolic pathology where light to moderate physical exercise exertion is medically contra-indicated.
- Bone fractures or other musculoskeletal conditions in which mobilization of pelvic floor muscles or lower limbs is contraindicated.
- Aphasia, dementia or any other psychiatric comorbidity that interferes with the use of the medical device.
- Complicated or high-risk pregnancy
- Pelvic health complaints related to conditions outside of the program's coverage: i.e.- untreated, active pelvic inflammatory disease (PID).

In addition, the use of Sword Bloom is contraindicated in the presence of continuity solutions or other local complications affecting the vagina.



Precautions

Only use Sword Bloom for its intended use as described in this manual. It should not be used as a treatment or preventive measure for any medical conditions. If you have any doubts regarding its use, it is advised to consult with a licensed healthcare professional.

Before each use, examine both the Bloom Pod and the lubricant packaging (tube or sachet) for any visible damage, such as tears, punctures, or leaks. Ensure any tamper-evident seals or shrink-wrap are intact and have not been removed or altered. If you notice unusual changes in the lubricant, such as cloudy color, separation, or an off odor, do not use it. Should you find any damage or evidence of tampering, discontinue use and contact our Customer Care Team at help@swordhealth.com (in the US) or helpuk@swordhealth.com (in the UK).

This is a single-user product. The use of this device by more than one person may present a health risk.

Do not use the Sword Bloom if:

- You have given birth within the last six weeks.
- You have a complicated or high-risk pregnancy.
- You have a medical condition affecting your pelvic health (for example, abnormal vaginal discharge or severe prolapse) and have not spoken to your Bloom pelvic health specialist or have not been cleared by a medical provider.

Do not use the Bloom Pod if:

- You are pregnant.
- You experience persistent pain when inserting or using the Bloom Pod.
- You are allergic to medical-grade silicone.
- The Bloom Pod has been modified, damaged, and/or tampered with.

The Bloom program is not designed to be used by those with a complicated or high-risk pregnancy. If you wish to use the Bloom program during your pregnancy, you should first consult with your physician or other qualified health provider prior to participation. Insertion of the Bloom Pod during any stage of pregnancy is not a requirement for participation in the program and is discouraged.

Do not leave the Bloom Pod inside your vagina for more than half an hour at a time.

The Bloom Pod is made with medical-grade silicone. However, if you experience skin irritation, discontinue use immediately and consult a healthcare professional.

During normal use, the temperature on the applied part of the Bloom Pod can reach up to 41.5°C.

The Bloom Pod is completely covered in medical grade silicone with no exposed parts, being safe to use with most intrauterine devices (IUD). However, it is recommended that you consult with a licensed healthcare professional before using the Bloom Pod if you have an active implanted device that would be affected by a magnetic field (e.g. IUD, pacemaker, implantable cardioverter defibrillator).

The Bloom Pod is safe to use during menstruation. As with general usage, follow the cleaning guidelines. Additionally, throughout your menstrual cycle, your intravaginal pressure range may vary — it's just a natural fluctuation in your strength as part of your monthly cycle.

Bloom Pod is not a substance-based device and the materials used are compliant with REACH, Prop65, and RoHS.

Use of the Bloom Pod adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The Bloom Pod uses Radio Frequency (RF) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The Bloom Pod is suitable for use in all establishments, including domestic establishments.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Bloom Pod. Otherwise, degradation of the performance of this equipment could result.

Bloom Pod was tested against the emission requirements of IEC 60601-1-2, being classified as Class B, Group 1. It passed the testing for all of the following: Radiated RF Emissions; equipment Immunity testing for EN 61000-4-2 Electrostatic Discharges and the IEC 61000-4-3 Radiated RF EM Fields and IEC 61000-4-3 Proximity Wireless fields, IEC 61000-4-8 Power frequency magnetic field, IEC 61000-4-39 Radiated fields in close proximity immunity test with levels defined for home healthcare environment in accordance with IEC 60601-1-2 2015 and IEC 60601-1-2 AMD1_2020.

Unique Device Identifier (UDI)



The UDI is the unique device identifier which is a regulatory requirement and is displayed in full on the 'Instructions For Use' page for the mobile version. The last five digits indicate the software version of Sword Bloom with 'X' denoting the major software version, 'Y' denoting the minor software version and 'Z' denoting patch version.

UDI: (01)05065013876023(8012)7.Y.Z



This software product is classed as a medical device

Explanation of the symbols on the Sword Bloom IFU and on the label	
	Consult Sword Bloom Instructions for Use
	Manufacturer
	Date of Manufacture
	Catalogue Number
	Batch Code

	Caution, there are specific warnings or precautions associated with the device which are not found on the label – consult the instructions for use (if applicable)
	Medical Device
	Unique Device Identifier in both readable plain-text and Automatic Identification and Data Collection (AIDC) technology (2D-matrix) formats
	UKCA Marking under UK MDR 2002
	UK Responsible Person (UKRP)

Help and Support

In the event of any serious incident occurring in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

For patients, please communicate this through your Women's Health Specialist who will notify Sword Health (the manufacturer) directly without delay.

For assistance, you can also email our Support team at help@swordhealth.com (in the US) or helpuk@swordhealth.com (in the UK).

If you require a printed copy of these Instructions for Use, please contact Sword Health's Support team.

The product label can be found under the "About" menu section.

What does the app do?

The Sword Health App is a native mobile application that connects to the Bloom Pod, processes the data it collects, and provides real-time feedback to guide you through your exercises. If the app detects incorrect movements, it will prompt you with corrective guidance to help you perform the exercises properly.

The Sword Health App also syncs your session results to the Clinical Portal. This allows your Women's Health Specialist to monitor your progress and adjust your program as needed. In order to fully operate, the Sword Health App requires an active internet connection (via Wi-Fi) to synchronize your data. The smartphone running the app must have Bluetooth Low Energy (BLE) enabled to connect and communicate with the Bloom Pod.

How do I use the app?

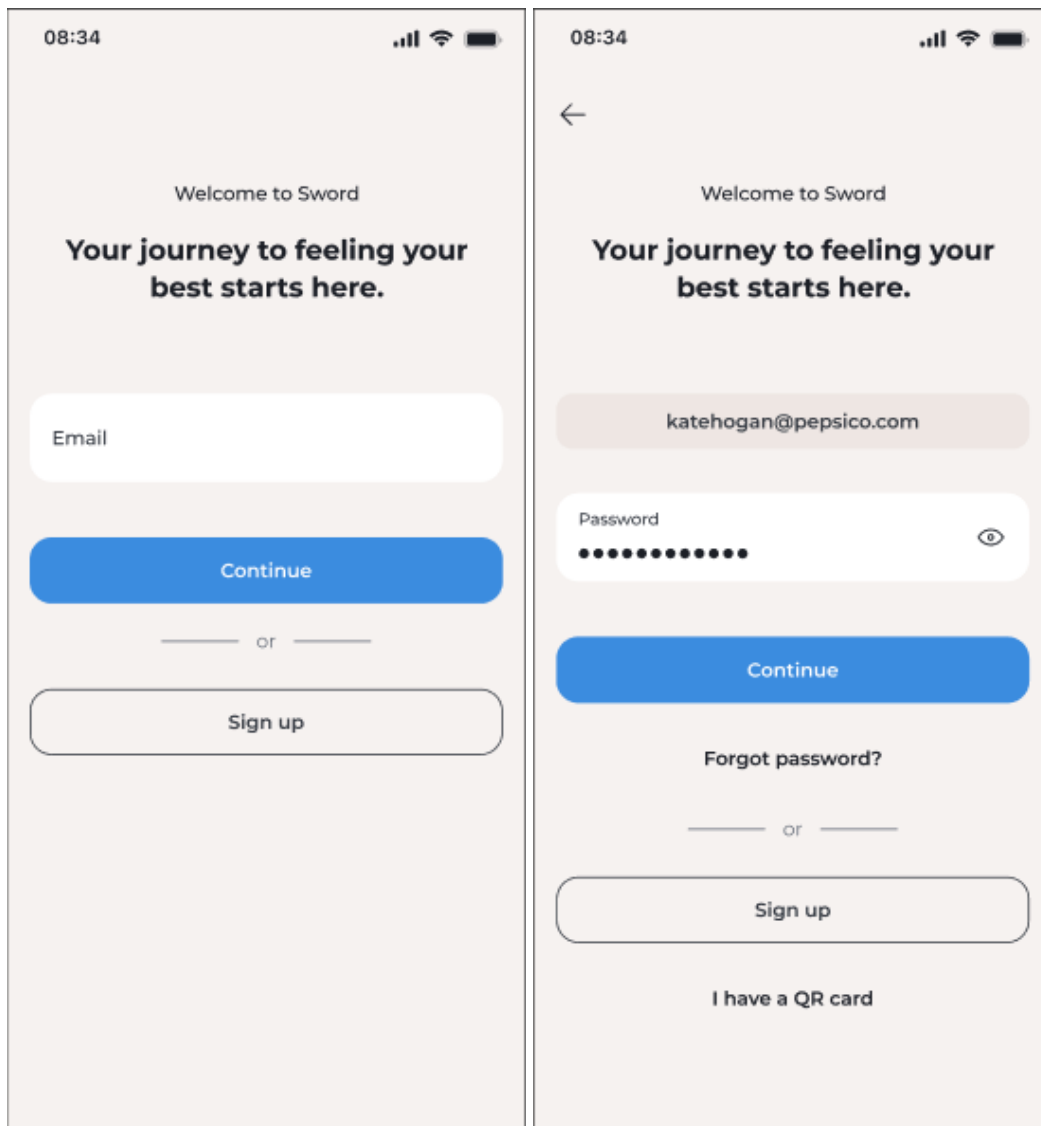
Perform pelvic floor exercises

Download the Sword Health app to connect your Bloom Pod. Open the app.

Login

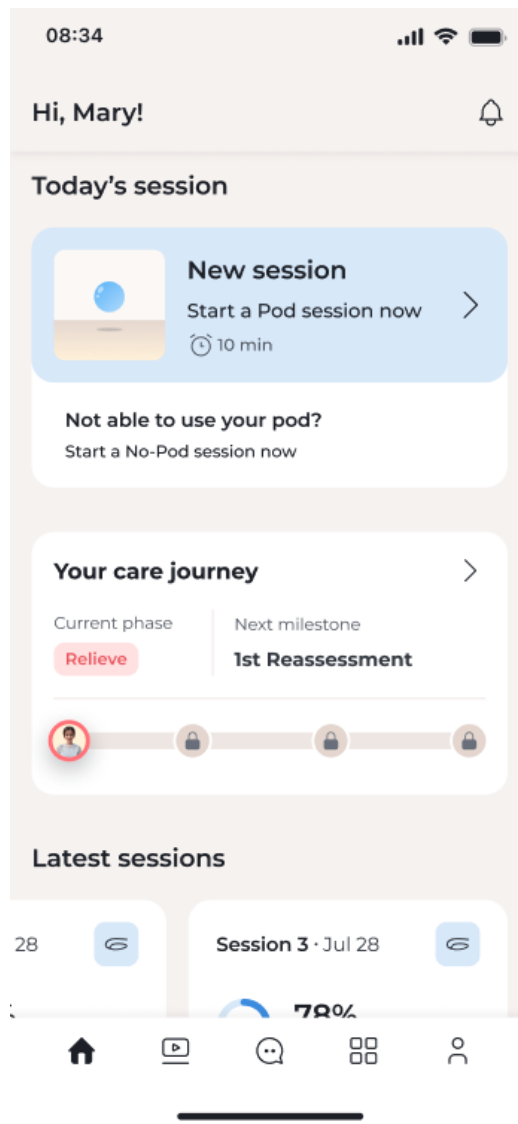
Use your account credentials to login (email and password defined during the enrolment flow when you decide to start your therapy).

1. If you forget your password: choose the option "Forgot password?", the app will guide you through a flow where you will receive an email to update your password. After password re-definition you can login.
2. If you insert an incorrect password several times your account will be temporarily locked.

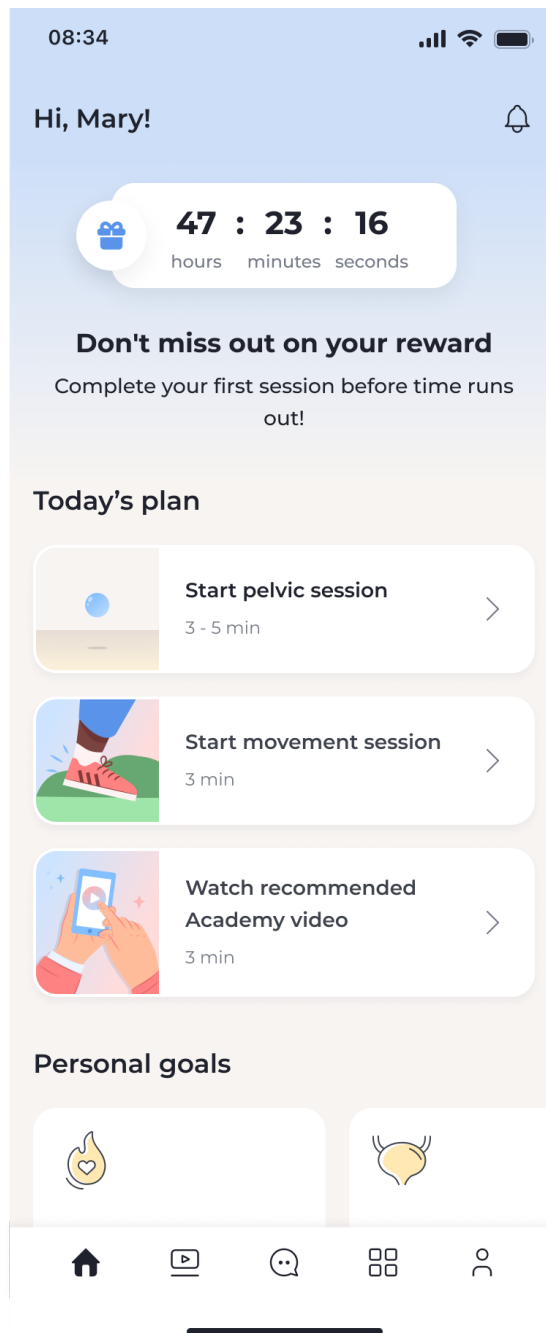


Homescreen

The home screen of the app shows the member care journey path, results of past sessions, personal goals, and an entry point to perform sessions.

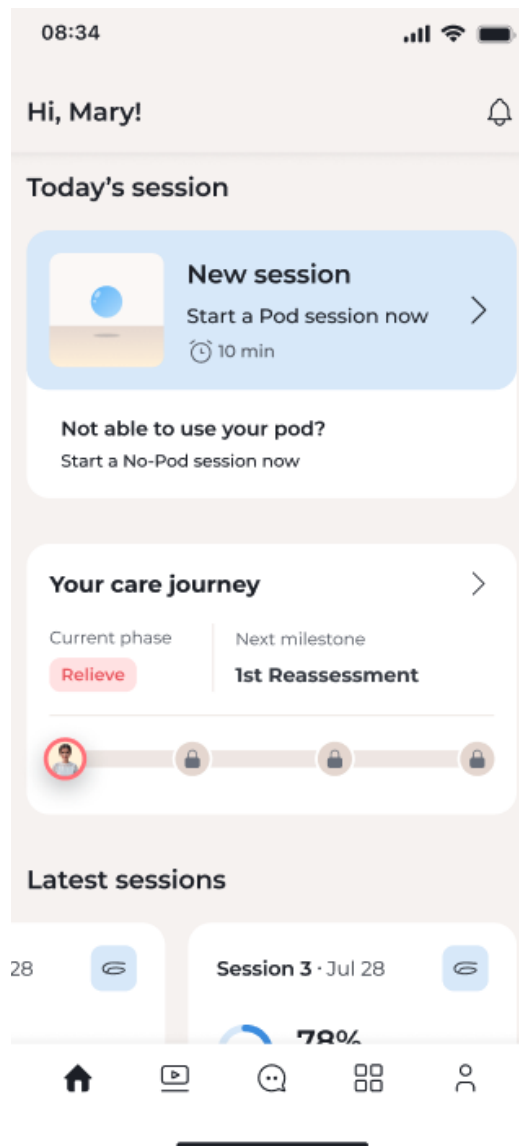


There is also a version of the homepage, specific for the menopause program, where members can start Pelvic sessions, mindfulness sessions or movement sessions.

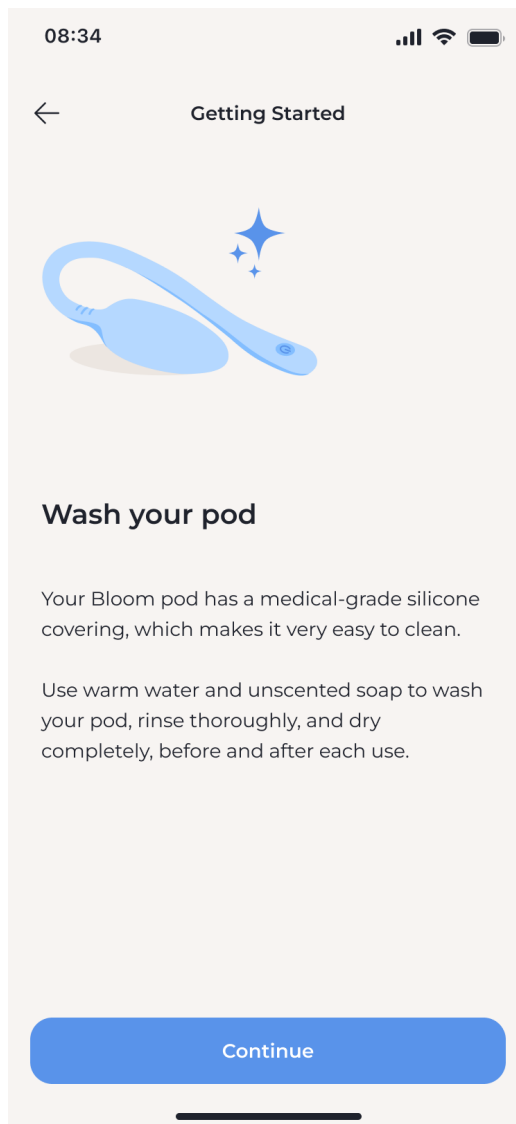


Pod session

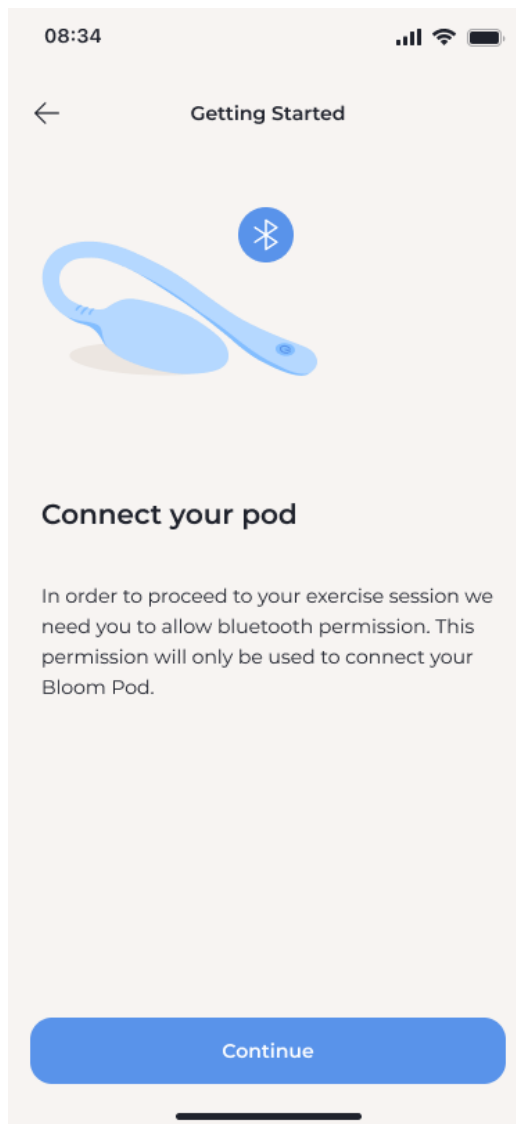
1. On the app homepage, there is a section "Today's session". To start a session with the pod, click on the blue "New session" card.

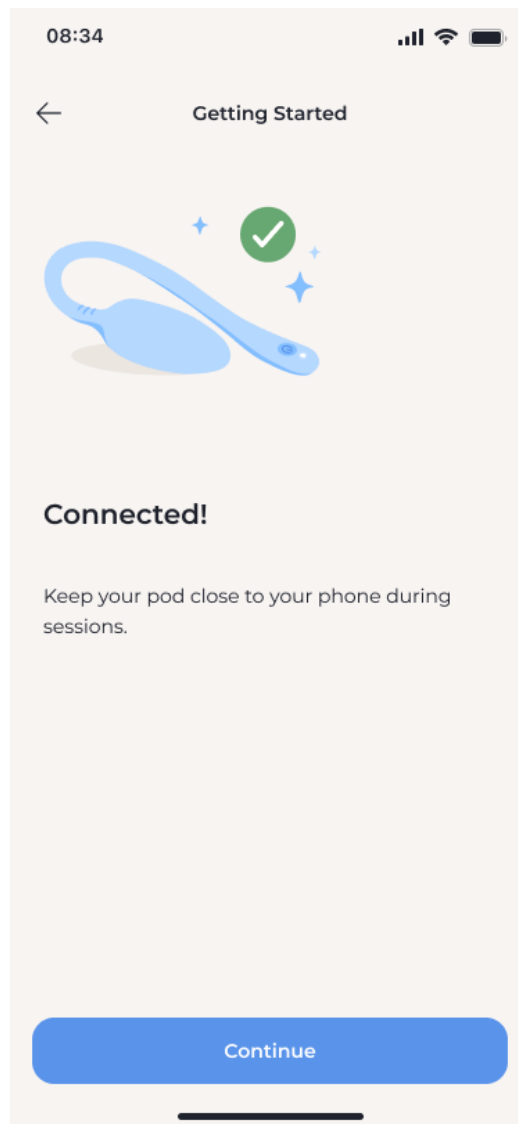


2. The app will ask you to wash your pod before a session.

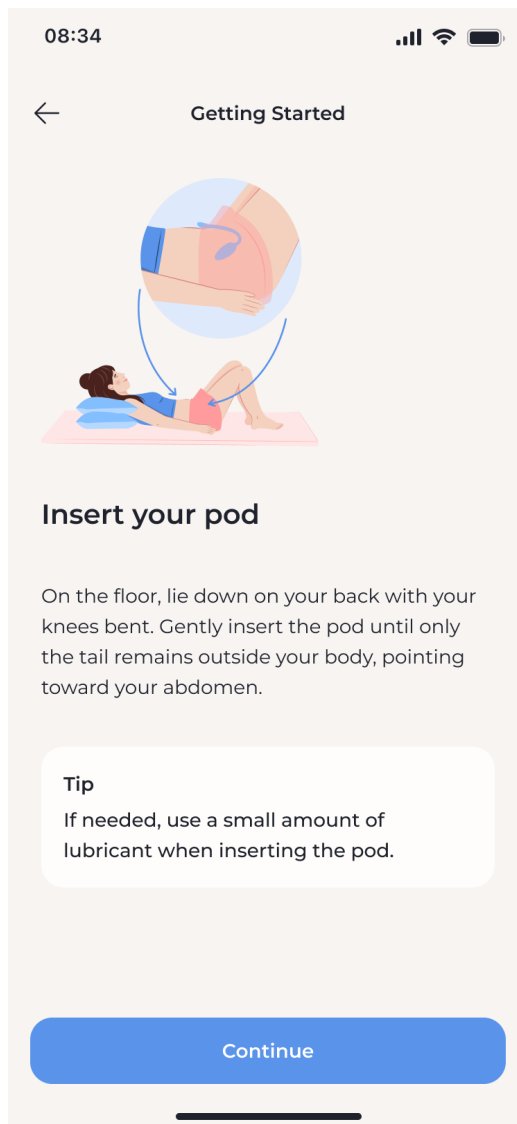


3. Connect your Pod to the Sword Health app: In order for the Pod to be connected ensure both bluetooth and location permissions are allowed. Permissions should only be requested on the first Pod session.

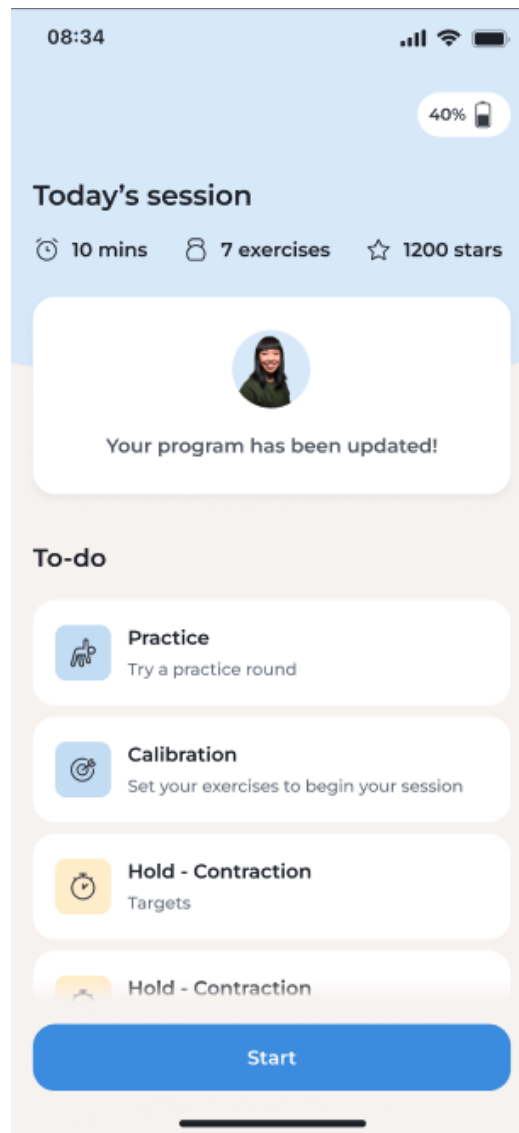




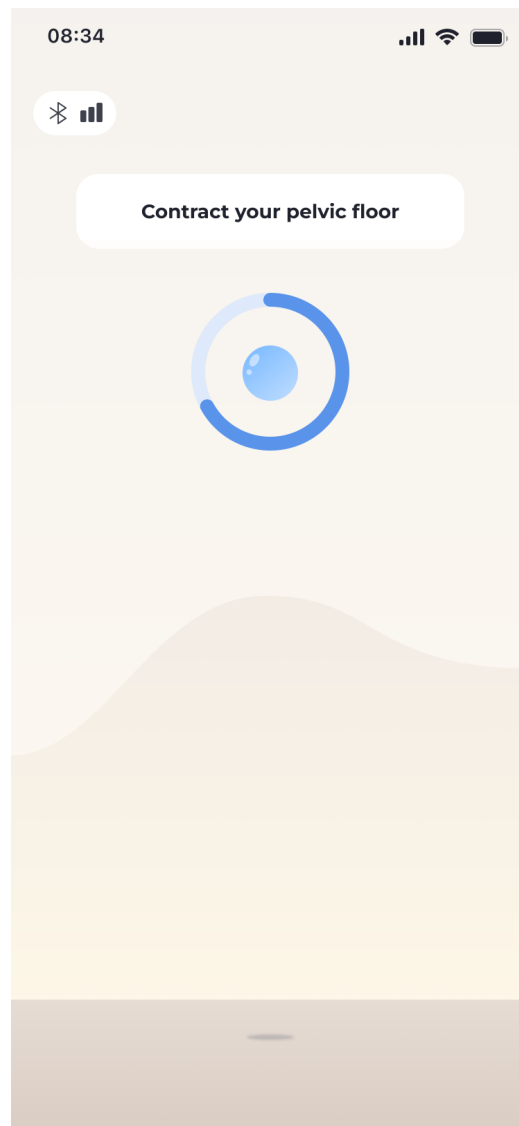
4. Insert your Pod: Lying down, insert your Pod ensuring the tail of the Pod remains outside of the body.



5. The session preview screen shows a resume of the activities and exercises of the session.

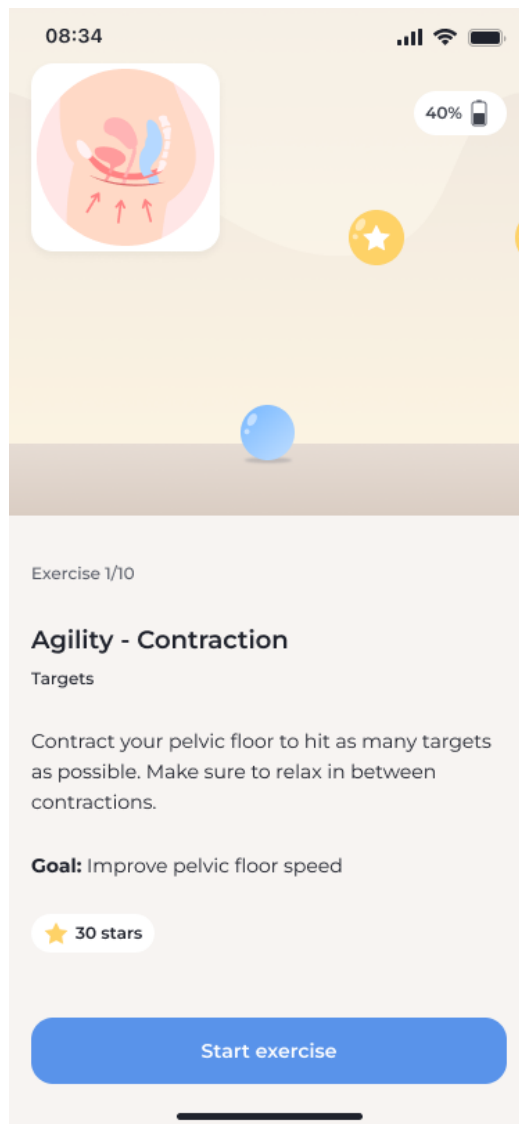


6. Calibration: Calibration is necessary to allow the app to understand the relaxation baseline for the member, as well as their maximum contraction range.



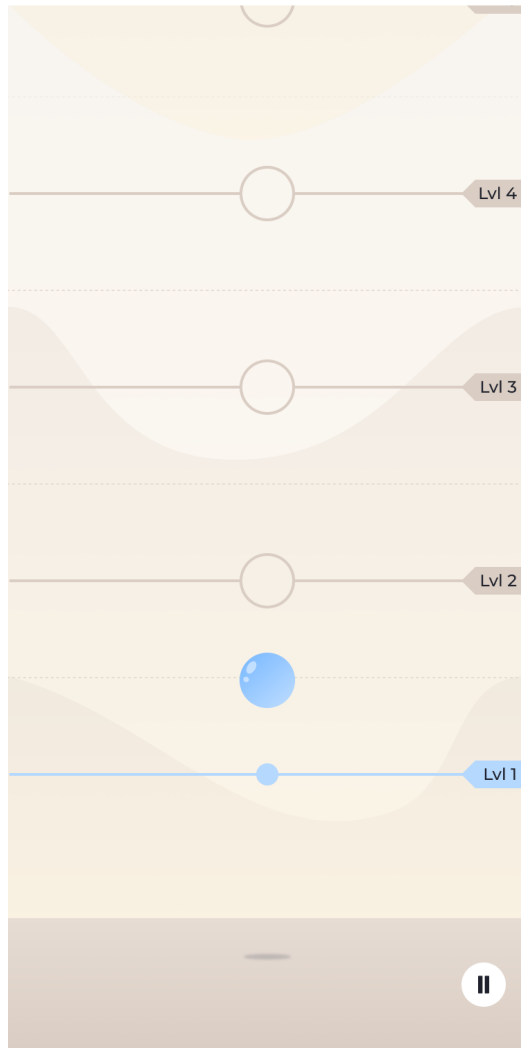
7. Exercises:

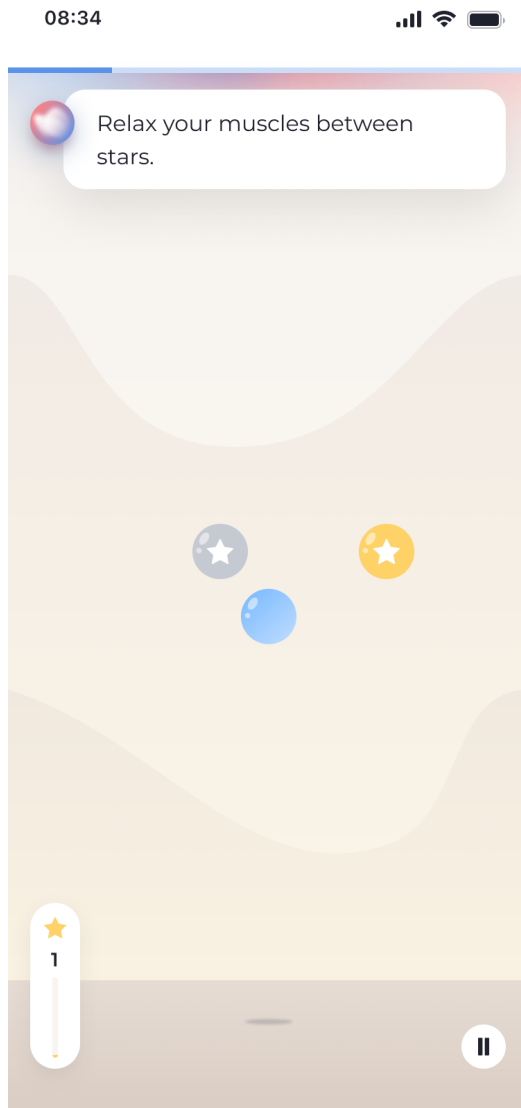
- a. Exercise preview: The exercise preview explains briefly how to perform the exercise and shows the exercise goal:

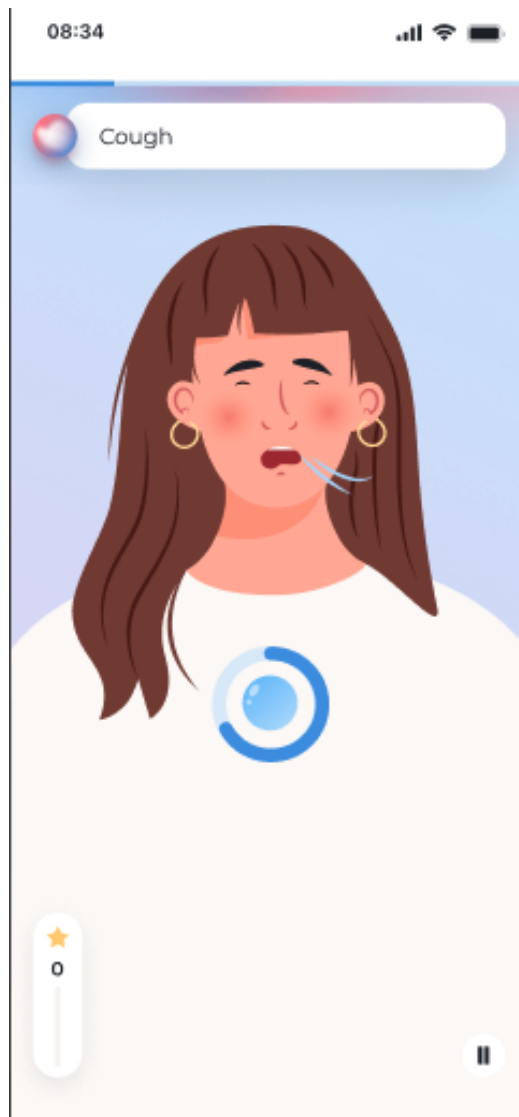


- b. Exercises: During the exercises the app will display a game, and performance is tracked through the feedback received by the intravaginal Pod. Instructions and auxiliary feedback are displayed accordingly.

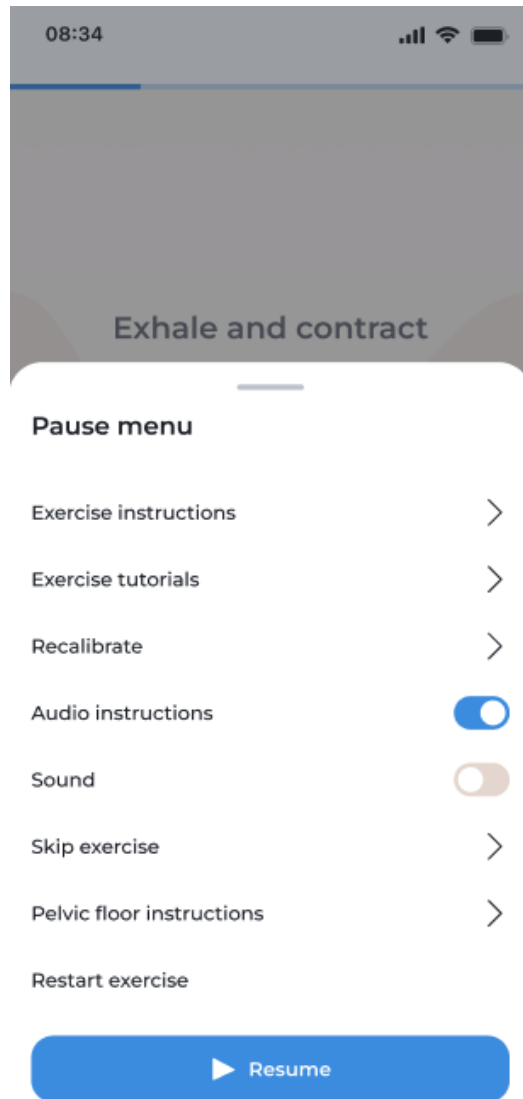
08:34



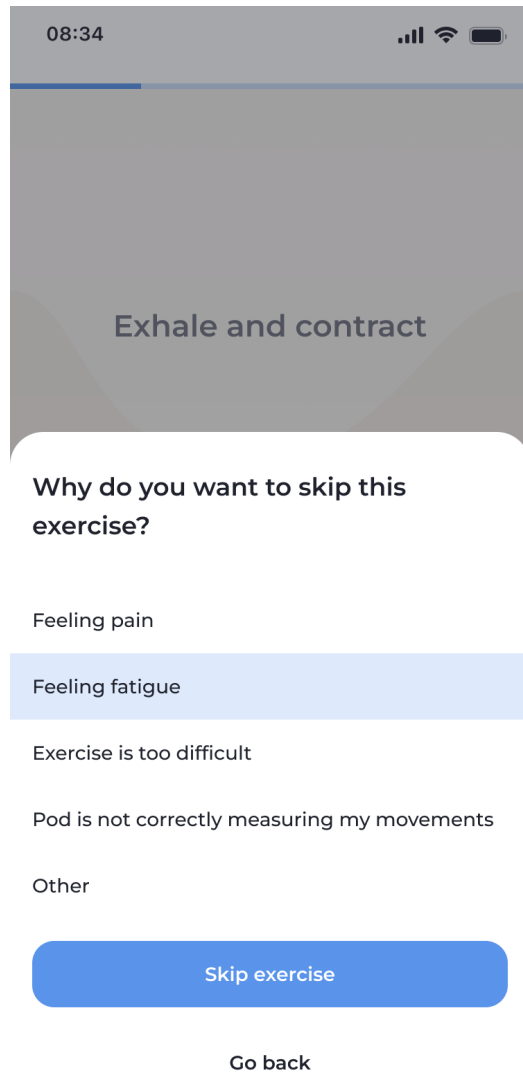




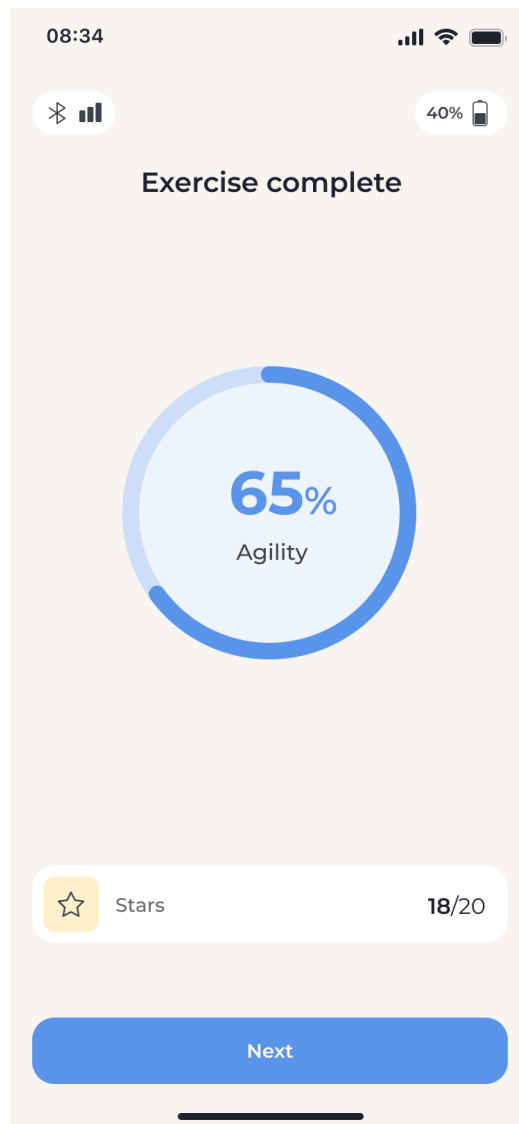
- c. Exercise Actions: While performing the exercises, some actions are available when clicking on the pause button:



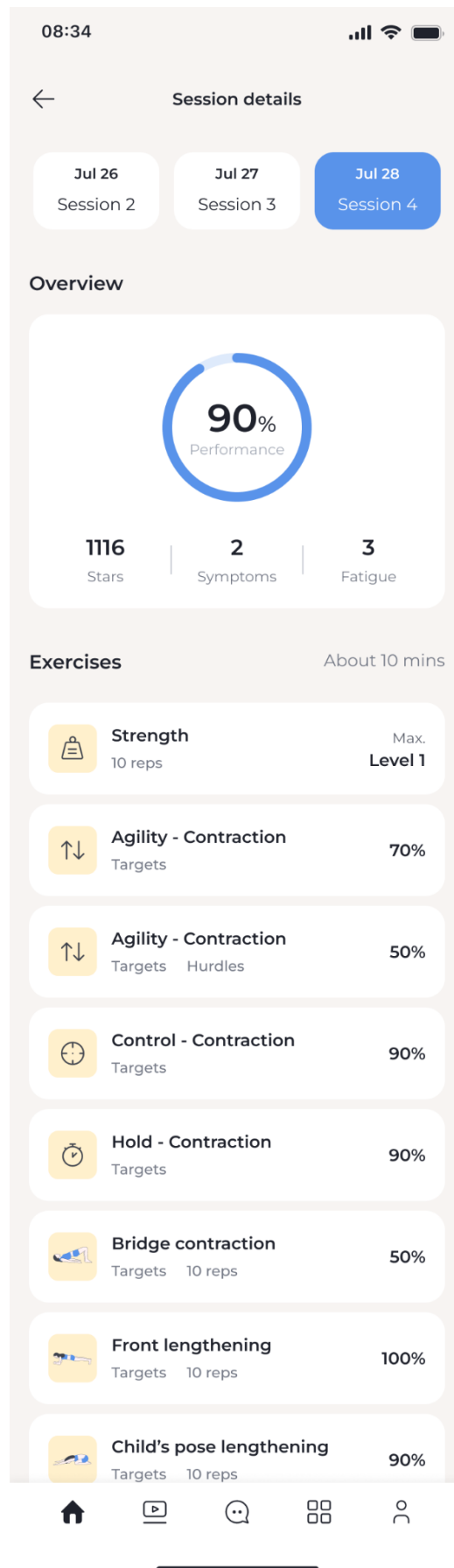
- i. Exercise instructions: Shows the exercise preview screen.
- ii. Exercise tutorials: Shows the exercise tutorials, if available for that exercise.
- iii. Recalibrate: Allows the user to perform the calibration step again.
- iv. Audio instructions: Allows the user to turn on and off the audio instructions.
- v. Sound: Allows the user to turn on and off the audio from the game.
- vi. Skip exercise: Allows the user to skip the exercise. In this case a reason must be given.



- vii. Pelvic floor instructions: Shows the user a set of screens explaining how to contract, relax and lengthen the pelvic floor.
- viii. Restart exercise: Allows the user to restart the exercise.
- d. End of exercise: When the exercise is completed, a screen with the exercise overall performance is shown:



8. Session results: When the last exercise of the session is completed, the session results are shown. The session details page shows the overall performance of the session and detailed performance on each individual exercise.



9. Quality questionnaire: At the end of the session a quality questionnaire is displayed for the user to rate the session experience: questions on symptoms, fatigue and overall session quality are asked to the user.

08:34



40%

How did you feel during today's session?

Please share any physical challenges with your Specialist via chat

Symptoms during today's session

3

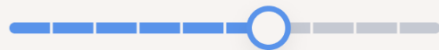


None

Extreme

Fatigue during today's session

6



None

Extreme

How would you rate your experience today?



Satisfied

What affected your experience today?

Too easy

Too hard

Too fast

Too slow

Exercise tracking

Pod slipping

Pod connection

Other

0/150

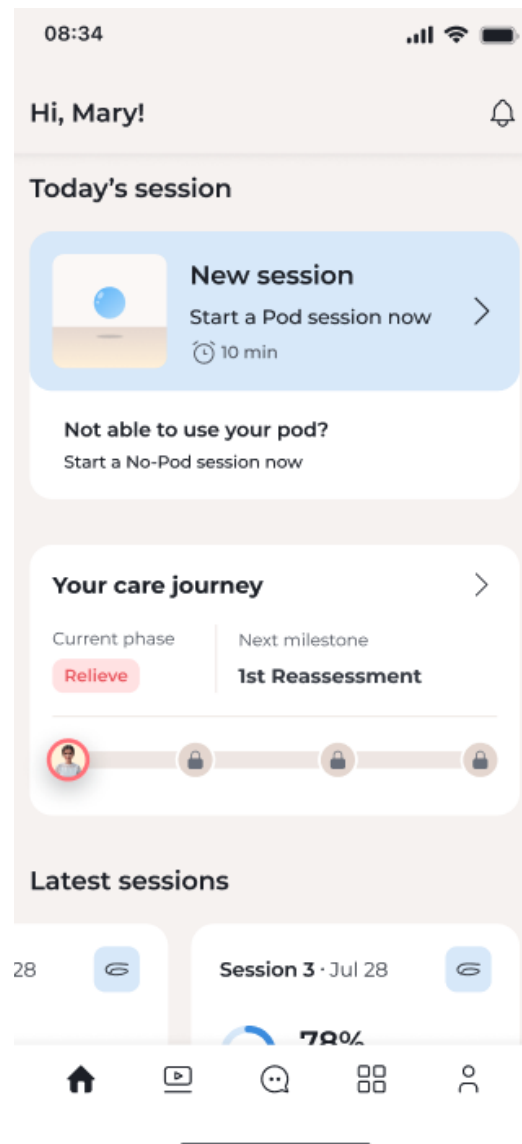
Share your feedback here (optional)

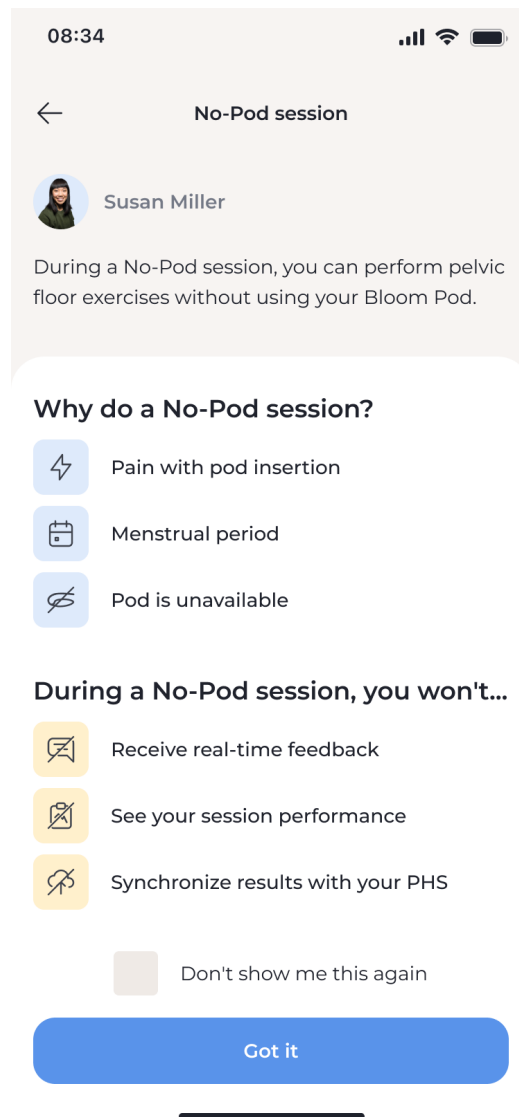
Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut

Submit

No Pod session

1. On the app homepage, there is a section “Today's session”. To start a session without the pod, click on the white “Not able to use your pod? Start a No-Pod session now” card. A screen is shown explaining the purpose of the no pod sessions. Then, another screen collects the reason on why the member is performing a no pod session.





08:34

← No-Pod session

Why are you performing a No-Pod session?

I'm traveling / I'm on the road

I don't have my pod with me

I'm having technical issues with my pod

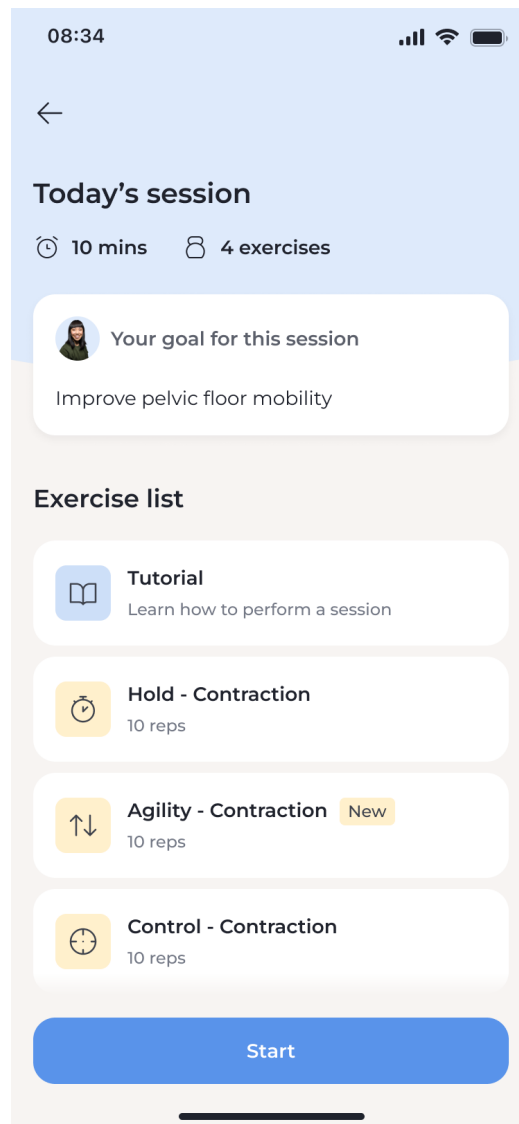
I have pain with pod insertion

I'm on my period

Other

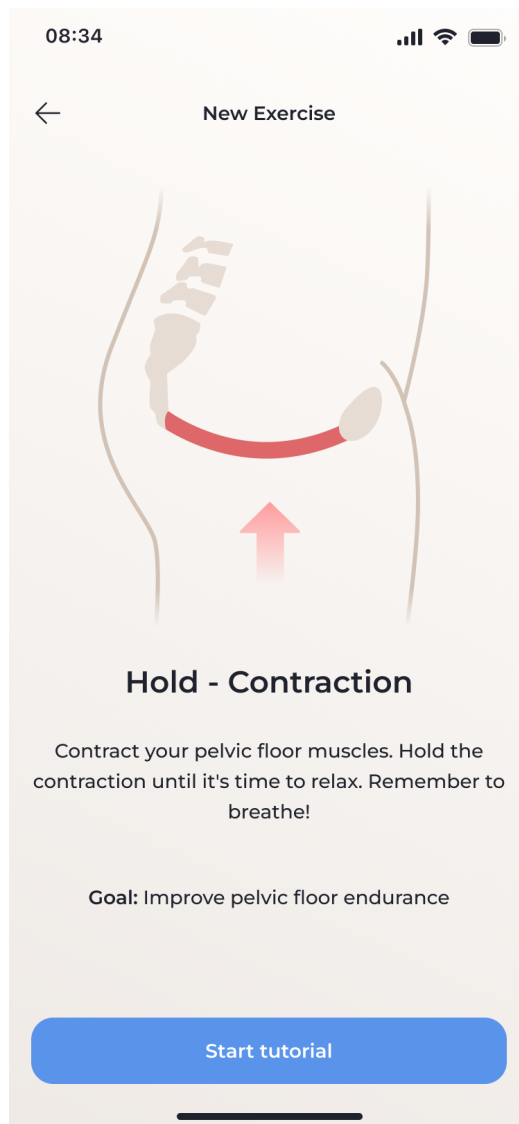
Continue

2. The session preview screen shows a resume of the activities and exercises of the session.

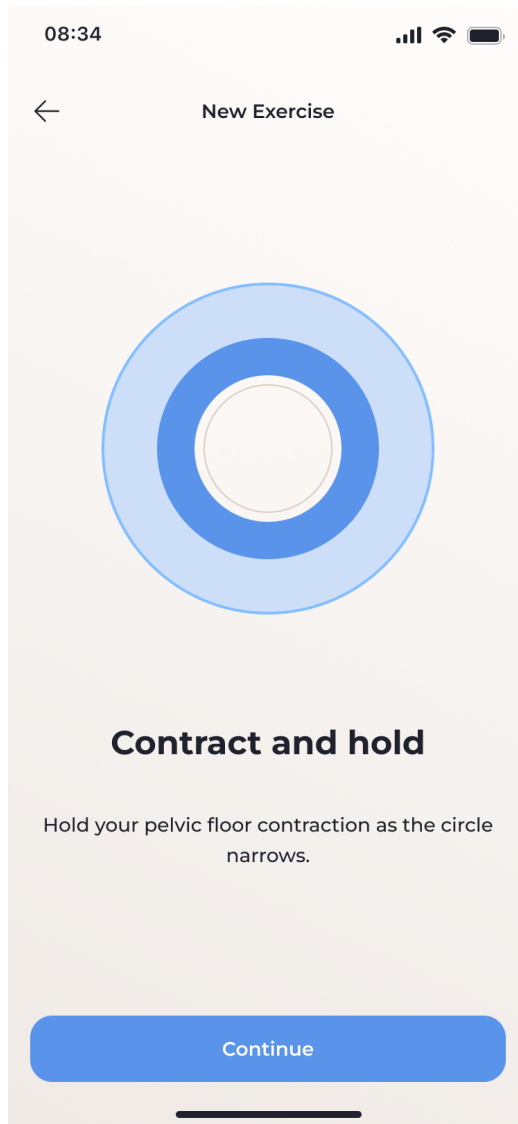


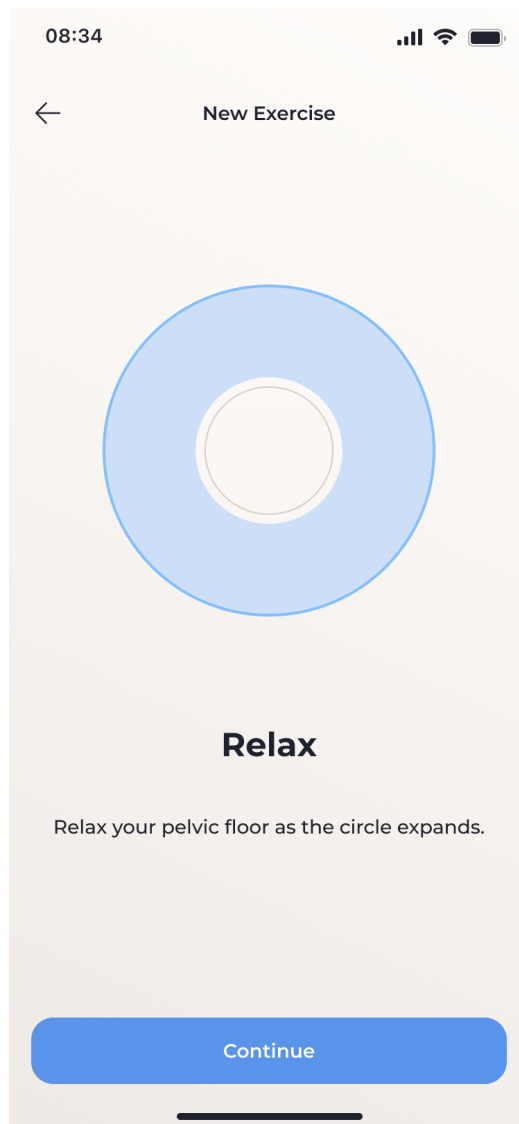
3. Exercises:

- a. Exercise preview: The exercise preview explains briefly how to perform the exercise and shows the exercise goal.

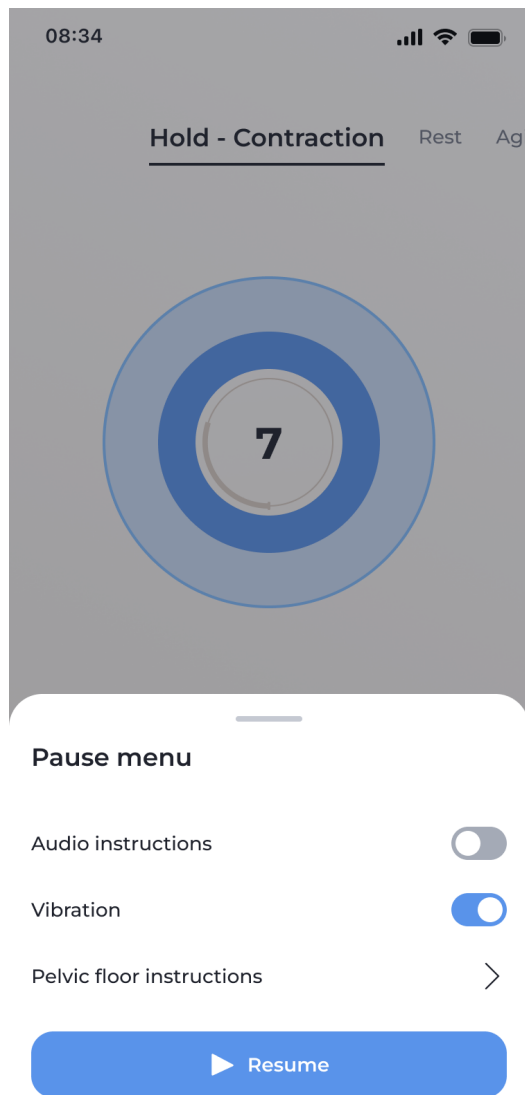


- b. Exercises: During the exercises the app will display instructions, along with animations, to guide the user through the exercise.

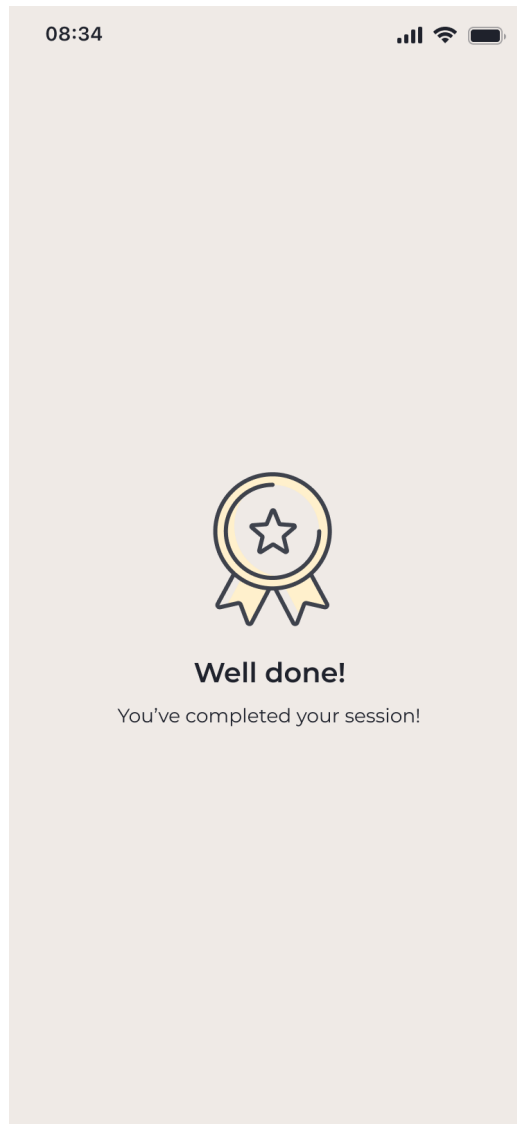




- c. Exercise Actions: While performing the exercises, some actions are available when clicking on the pause button:



- i. Audio instructions: Allows the user to turn on and off the audio instructions.
 - ii. Vibration: Allows the user to turn on and off the vibration..
 - iii. Pelvic floor instructions: Shows the user a set of screens explaining how to contract, relax and lengthen the pelvic floor.
4. Session completed: when the session ends, the session completed screen is shown.



5. **Quality questionnaire:** At the end of the session a quality questionnaire is displayed for the user to rate the session experience: questions on symptoms, fatigue and overall session quality are asked to the user.

08:34



Well done!

You've completed your session!

How did you feel during this session?

Please share your feedback below.

Pelvic-health symptoms

3



Fatigue

6



How would you rate today's session experience?



Satisfied

120/150

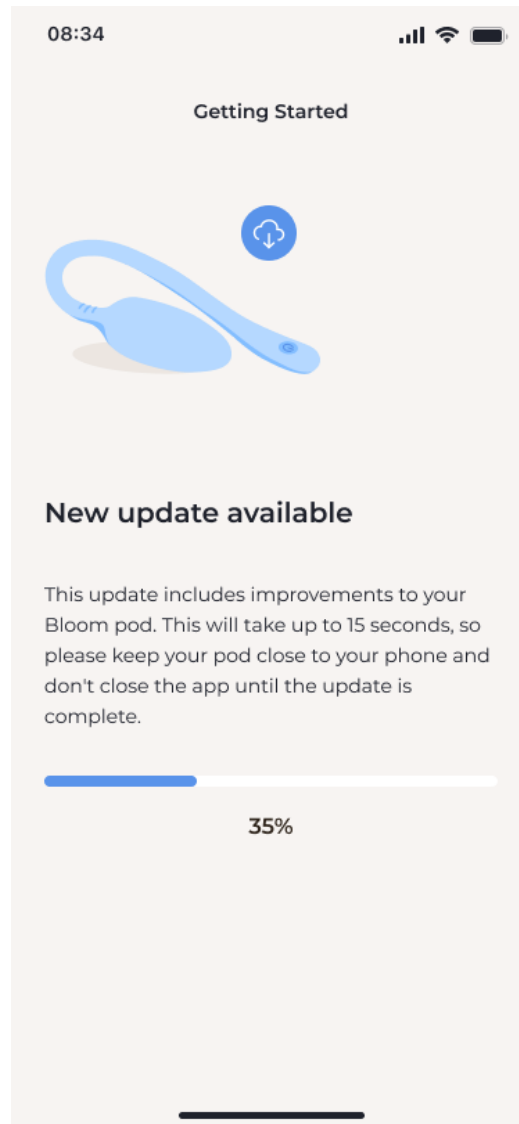
Share your feedback here

Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut

Submit

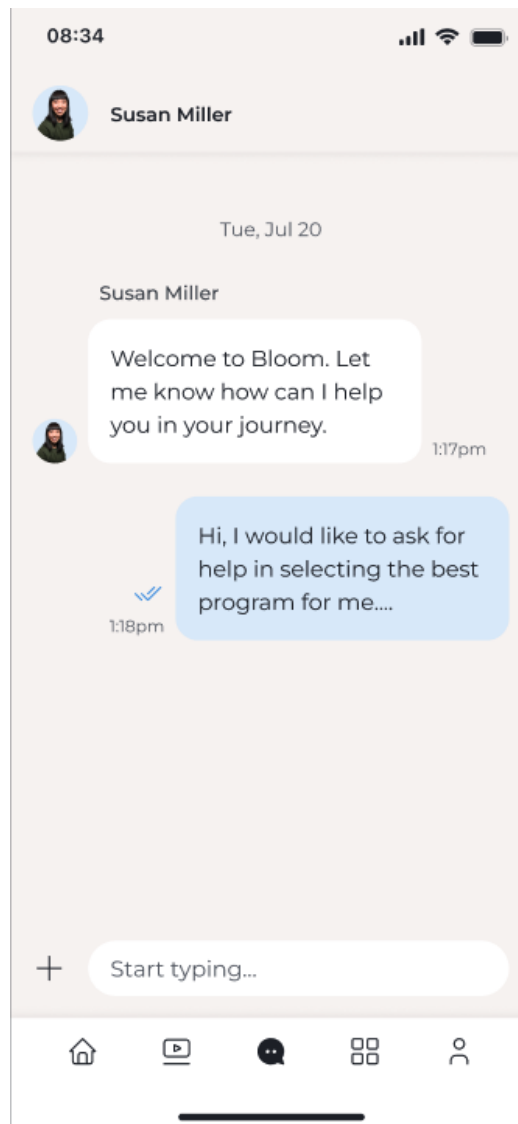
Bloom Pod updates

1. If you use your app on a regular basis, it is likely that you will receive updates when the session starts. This process doesn't require user interaction.



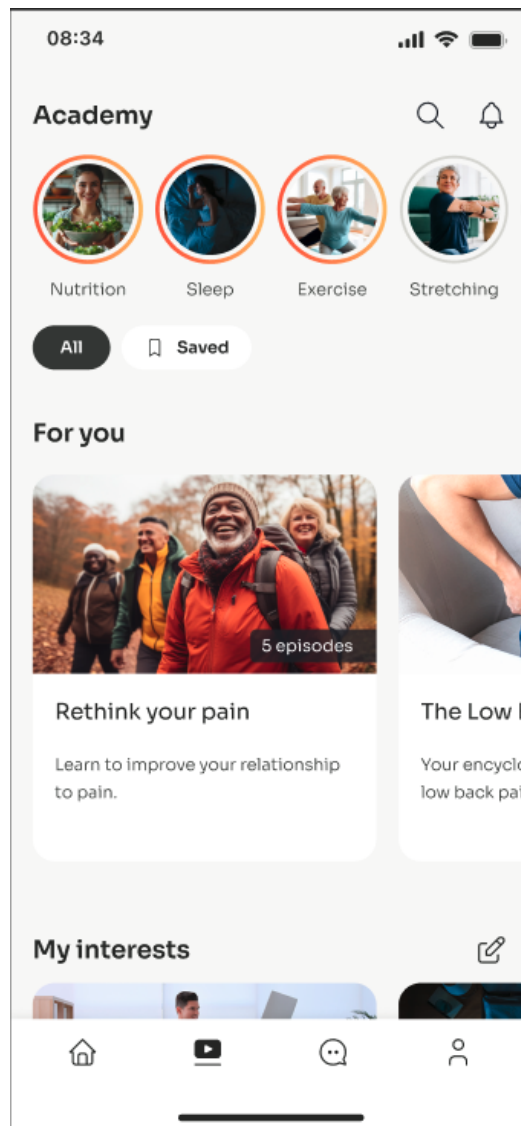
Chat with your Women's Health Specialist

Your Women's Health Specialist is available through the chat in the app.



Learn more about your health condition

Academy is a section on the app with educational videos on health conditions, exercise, nutrition, sleep and overall wellbeing.

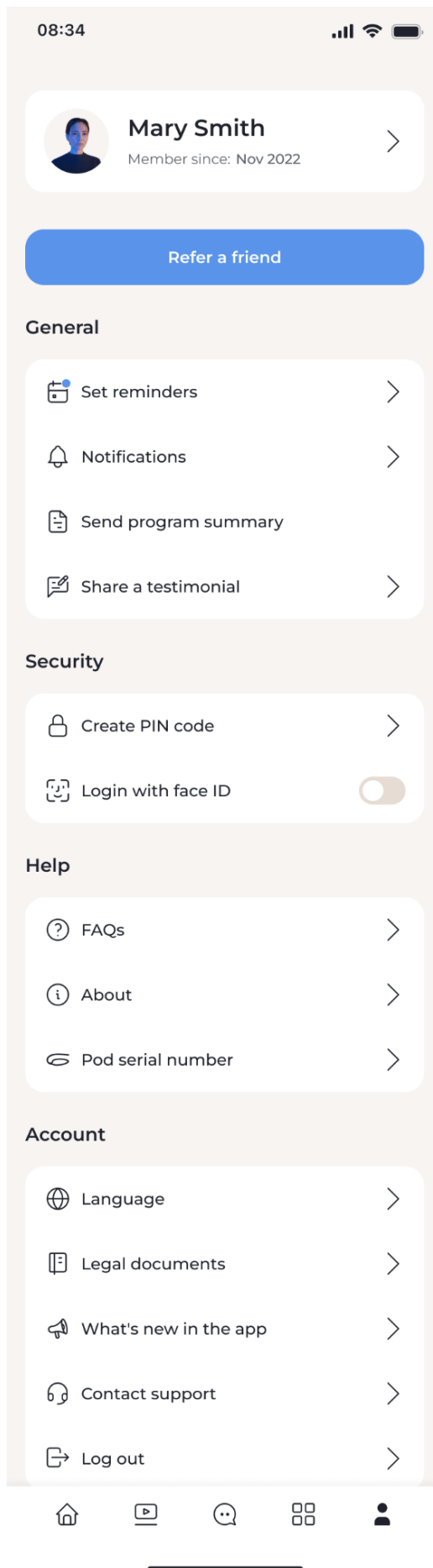


Customize the Sword Health app

On the profile page of the Sword Health app the user can:

- Set reminders to perform sessions
- Configure notifications
- Configure language

The user can also access the legal documents and FAQs, contact support, create a pin code, share a testimonial, log out amongst others.



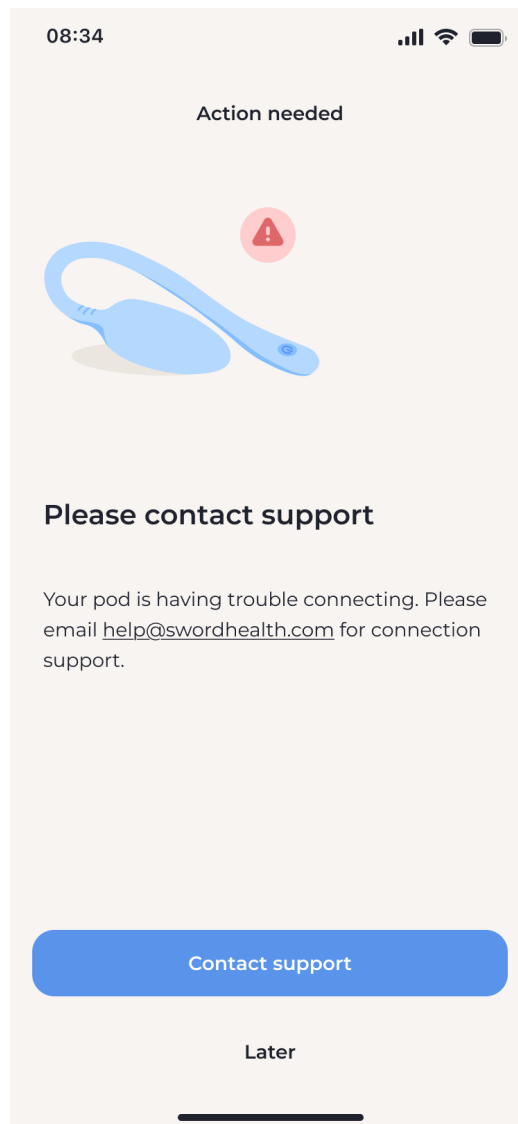
Troubleshooting

What do I do if the app is not working?

If you have trouble setting up your Pod or using it, email our Support team at help@swordhealth.com (in the US) or helpuk@swordhealth.com (in the UK). You can also message your Women's Health Specialist on the "Chat" tab on the Sword Health app.

What do I do if I can't connect the Pod?

If you're having trouble connecting your Pod, please contact us at help@swordhealth.com (in the US) or helpuk@swordhealth.com (in the UK).



Can the Sword Bloom provide a patient diagnosis?

No. The Sword Bloom detects movement, the results analysis is performed by a Women's Health specialist, who concludes the progress/effectiveness of a certain pelvic health routine adjusted to the patient's diagnosis.

Can I send a message to my Women's Health Specialist?

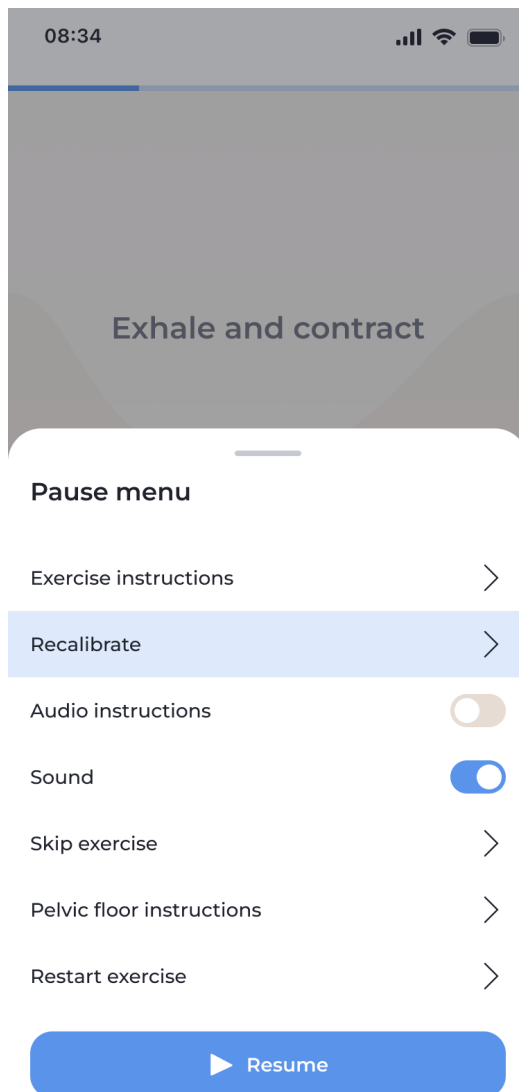
You can message your Women's Health Specialist on the "Chat" tab on the Sword Health app.

Can I send a message to the Sword Health Support team?

You can message our support team through the profile page of the Sword Health app or by sending an email to help@swordhealth.com (in the US) or helpuk@swordhealth.com (in the UK).

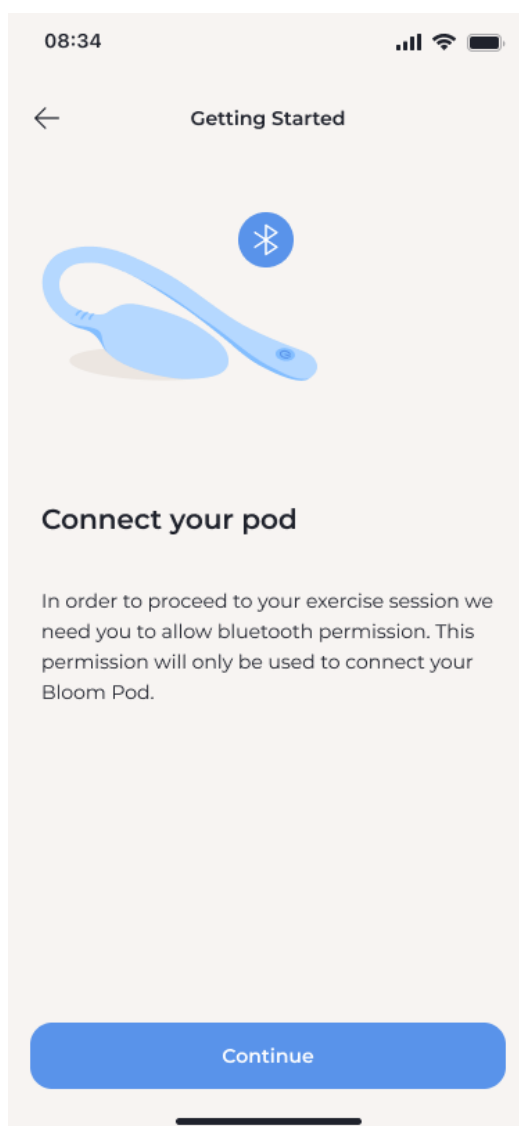
How do I ask for a recalibration?

You can request a recalibration at any time during an exercise. This option is available in the pause menu.



Can I cancel a session?

You have an option to leave the session before it starts, clicking on the back arrow buttons.



How long do I have to use the app?

The goal of the app is to guide you through an exercise program that can improve your quality of life and tackle pain, discomfort or disability related to your pelvic floor. Because everyone has different goals and needs, the length of your program can vary. Your Women's Health Specialist will help you determine how long you need to use the app for. Users of the app typically start noticing improvements as early as 3-5 sessions, but 9 sessions are usually the minimum number of sessions that we recommend.

What happens when my session ends?

The app sends your session results to your Women's Health Specialist. The results will be analysed and your sessions will be adapted according to your performance.

Who can see my data?

Your data is shared with the Women's Health Specialist team who provides your care. Only authorised people are allowed to see your data.

The data that they hold includes:

- Data about you and your clinical information
- Data about your session (pelvic movement detection done by the system)

How do you protect my data?

We protect your data in several ways:

- Data is stored at rest and in backups using AES 256 encryption.
- Sword utilises the cloud provider's server-side encryption. The cloud provider manages keys.
- Access to data will be granted only to authorised users who are legally cleared to see data and on a 'need to know' basis.

Who can I contact with questions about my data?

You should contact your Women's Health Specialist initially. If you have any questions for Sword Health please contact our dedicated data protection officer by sending an email to dpo@swordhealth.com.

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