

## Instruction for use





Sword Health S.A. Avenida  
Sidónio Pais 153, Edifício A, Piso  
5, 4100-467 Porto, Portugal

**UK Responsible  
Person**

Sword Health UK Ltd, 6th floor  
One London Wall, London, EC2Y  
5EB, United Kingdom



**Digital Therapist™ Version 2**

Please note version number is equivalent of batch number

**Digital Therapist™**

A system intended to guide patients through a customised exercise rehabilitation program

**INSTRUCTIONS FOR USE**

Doc Ref: DT-IFUPUK-EN-02

## Table of contents

<b>Information for Patients</b>	<b>11</b>
<b>Indications for Use</b>	<b>11</b>
<b>Contraindications</b>	<b>11</b>
<b>Warnings</b>	<b>12</b>
<b>Unique Device Identifier (UDI)</b>	<b>13</b>
<b>Notice to User and/or Patient</b>	<b>13</b>
<b>What does the app do?</b>	<b>13</b>
<b>How do I use the app?</b>	<b>13</b>
App first use	14
What do I do if the app is not working?	18
What do I do if I can't connect the trackers?	19
What do the lights on my tracker device mean?	19
Can the Digital Therapist provide a patient diagnosis?	22
How do I set up the trackers?	22
Can I send a message to my Physical therapist?	23
Can I send a message to the Sword Health Support team?	24
How do I ask for a recalibration?	25
Should I recalibrate during an exercise session?	25
Can I cancel a session?	25
How long do I have to use the app for?	26

What happens when my session ends?	26
Who can see my data?	26
How do you protect my data?	26
Who can I contact with questions about my data?	27
<b>App setup</b>	<b>28</b>
Internet connection:	28
Login:	30
Read Physical therapist message	31
Start a session	32
Trackers connection	33
Place the straps and trackers	34
Trackers Calibration	35
Start an exercise	36
<b>Do an exercise</b>	<b>37</b>
<b>End a session</b>	<b>40</b>
Recommendations	41
Rate your pain/fatigue level after each session	42
Rate your experience	43
App/trackers update	44
<b>Home screen</b>	<b>46</b>
<b>Settings</b>	<b>47</b>

<b>Logout</b>	<b>48</b>
View the results from your sessions	48
Review how many sessions you have completed	48
Terms and conditions	48
<b>Troubleshooting</b>	<b>49</b>
How do I install the Sword Health app in my phone?	49
I can't see the results from my last session in the Sword Health app	49
I needed to change the placement of the trackers during a session	50
I can't perform an exercise	50
An app update is taking too long	50
My app keeps freezing	50
My app shut down mid-session	50
My tablet/trackers discharge too quickly	50
Appendix 1 - Camera Exercises	51

## Information for Patients

Digital Therapist™ is a medical device software (MDSW) intended to guide patients through a customised exercise rehabilitation program; monitor and collect information on the movement of body parts, including but not limited to lower limb, upper limb, pelvic, lower back, neck, wrist and provide real-time feedback to the patients on their performance. The exercise program that patients follow is designed, monitored, and adjusted by a qualified Physical therapist using their clinical knowledge based on patient diagnosis history, needs, and information collected by the device.

## Indications for Use

Digital Therapist™ is a medical device software (MDSW) designed to allow patients with MSK condition to undertake a rehabilitation program prescribed by the Physical therapist. It is primarily used to support restoring movement, function and muscle strength that has been affected due to injury, illness or disability including, but not limited to any one of the following parts of the body: Lower Limb, Upper Limb, Pelvic, Lower Back, Neck, Wrist.

Digital Therapist™ can also be used by healthy individuals who have not been affected by injury, illness or disability for general health and wellbeing purposes.

## Contraindications

Digital Therapist™ is intended to be used by patients above the age of 18, who have been recommended or prescribed a course of exercise as physical therapy by a suitably qualified professional with experience in physical therapy.

Digital Therapist™ is not designed to be used by patients presenting with any of the following conditions:

- Symptoms/signs compatible with active joint infection
- Symptoms/signs compatible with acute and serious neurological compromise
- Hyper-acute stroke (first 48 hours)
- Hemodynamic instability
- Respiratory, cardiovascular or metabolic pathology where light to moderate to moderate physical exercise exertion is medically contra-indicated

- Bone fractures or other musculoskeletal conditions in which mobilisation of the segment or joint is contra-indicated
- Aphasia, dementia or any other psychiatric comorbidity that interferes with the use of the medical device
- Any other contraindication determined by the Physical therapist during patient's assessment

In addition, the use of the Digital Therapist™ is contraindicated in the presence of cutaneous lesions or continuity solutions in the area where the motion trackers would have to be in contact with.

## Warnings



- To minimise allergic reactions, don't place the straps directly on your skin when possible.
- Do not use any accessory, detachable part, or/and material not requested by the system.
- Keep any component away from pets or children, as they may break or cause injury.
- Do not expose the provided motion trackers or tablet to water. If exposed, do not use it and contact Sword Health's Support team [help@swordhealth.com](mailto:help@swordhealth.com)

## 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 Digital Therapist™ with 'Y' denoting the minor software version and 'Z' denoting patch version.

UDI: (01)05065013876009(8012)2.Y.Z



This software product is classed as a medical device

## Notice to User and/or Patient

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 Physical therapist who will notify Sword Health (the manufacturer) directly without delay.

If you require a printed copy of these Instructions for Use, please contact Sword Health's Support team [support@swordhealth.com](mailto:support@swordhealth.com)

## What does the app do?

Digital Therapist is a software medical device with accessories that will guide you through your customised exercise rehabilitation program. The Device monitors and collects information on the movement of body parts and provides real-time feedback on patients' performance. The exercise program that you will follow is designed, monitored, and adjusted by a qualified Physical therapist using their clinical knowledge based on your needs and information collected by the Device.

## How do I use the app?

To use the app, follow these steps:

When you receive your system (before first use):

1. We recommend you charge the tablet. The display will show when it is fully charged
2. Charge the trackers. The trackers will show a green light when they are fully charged and display a blinking yellow light while they are charging.
3. Shake the trackers to display a blue light, they are now ready to be connected to your device (tablet).

Once you turn the device on, the Digital Therapist app will be ready to use.

## App first use

### Internet connection:

1. When you first use the App it will ask you to connect to a wifi network.
2. Choose the network to connect when the App shows the networks available to connect.
3. Insert your network password.
4. With a stable internet connection the device will be able to send session data to your Physical therapist.

Note: Contact Sword Health support if you don't have wifi at home.

### Login and setup:

1. Use your account credentials to login (email and password defined during the enrolment flow when you decide to start your therapy).
  - a. 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.
  - b. If you insert an incorrect password several times your account will be temporarily locked.
2. After inserting your credentials the system will ask if you want to save your credentials for the next sessions.
3. The app ask you to take a photo and set the brightness level you prefer.
4. If your Physical therapist sends you a message it will appear.
5. You will have an opportunity to see an overview of the session before it starts.
6. App asks you to connect the trackers to a USB cable to turn them on (you can avoid this step if you charged your trackers before DT first use).
7. A connection starts via Bluetooth between the tablet and the trackers.

8. A video will start explaining how to place the straps and the trackers.
9. After these steps, the App asks to place the straps and the trackers on your body to start the calibration process.
10. Following completion of the calibration steps, you will be ready to start your session.

#### Daily routine - Starting the App:

1. If you choose not to save your credentials and your authentication expires, the App will ask to insert your password before starting a new session.
2. After several days of therapy, the App will ask you to answer the following question - "How much would you recommend the Sword system to someone".
3. You can/cannot have optional exercises before the session such as warm up exercises. During these exercises the system won't track your movement.
4. You can/cannot have a message from your Physical therapist to read before the session.
5. Before starting your daily session, you can see an overview of the session. By clicking "start" the App will start connecting the trackers to the device.

#### Trackers connection and calibration:

1. The app asks you to shake the trackers until they display a blue light. If when shaking the trackers, they don't display any light or they display a red light, you should charge them.
2. The connection is established when all the trackers have a green light.
3. The App will show you a warning message if your trackers don't have enough battery to do your session.
4. With the trackers connected the app will guide you to place the trackers on your body and do the calibration procedure.

Session:

1. Before every exercise you will have an explanatory video.
2. Each video has an option to pause.
3. The pause menu has an option where you can choose to leave your session.
4. When the demonstration video ends/when you choose to start, the App will ask you to “get ready”.
5. Before an exercise the App can request you to stay still on the correct initial position to save the position of the trackers on your body and improve the quality on movement detection,
6. During the exercises the app will guide you with corrections/demonstrations to help you achieve the best performance.
7. If the trackers lost the connection with the device during a session the App will restore the connection.
8. The app can will ask you to recalibrate during the session if the system notices a problem with your initial calibration (this could happen one time per session).
9. You can pause the exercise tapping the pause button.
10. During the exercise you can recalibrate or watch the demonstration video choosing the option on the pause menu. You can also choose to skip the exercise.
11. If you choose to skip the session or an exercise the App will ask you the reason between four different options.
12. When an exercise ends the App will show you your performance.
13. When the session ends the App will show you your performance.

End of session:

1. The system will ask about your pain/fatigue levels and how was your daily experience with the Sword system.
2. When the session ends you can choose to have some optional exercises to do without movement detection (such as stretches).
3. The trackers will be automatically disconnected.
4. The App will warn you when your device or trackers battery levels are low so you can re-charge them for your next session.
5. When not in use, the app goes to the Home Screen where you can choose to start a new session.
6. While on the Home Screen, the system sends the results of your session to your Physical therapist. It's important to keep the device ON and near your wifi router.

App updates:

1. If you don't use your app for a while, it is likely that you will receive an update once you connect your device.
2. If you use your app on a regular basis, it is likely that you will receive updates when the session ends. This process doesn't require user interaction.

Please refer to appendix 1 for further information on camera exercises.

## **What do I do if the app is not working?**

If you have trouble setting up your kit or using it, email our Support team at [help@swordhealth.com](mailto:help@swordhealth.com). You can also message your Physical therapist on the "Chat" tab on the Sword Health app. If you haven't already, download the app on your phone.

## What do I do if I can't connect the trackers?

Do the trackers have a blue light?

If your trackers have a blue light and it's not possible to connect them with your device, please restart the device and try again.

If the problem persists please contact the Support Team at [help@swordhealth.com](mailto:help@swordhealth.com).

Do the trackers have a red light?

Place your trackers into the charger, the trackers should show a blinking yellow light while charging. When they are fully charged they will show a green light.

Do the trackers display no light?

Shake your trackers. Once shaken, the trackers will show a blue light. If they do not show any light, place your trackers into the charger. They should show a blinking yellow light while charging. When they are fully charged they will show a green light.

If they do not show any light even when charging please contact the Support Team.

Do the trackers have a green light?

If the light on your trackers is green but the DT shows an error message, please place the trackers in the box on a stable surface and try again. If the problem persists, please contact the Support Team.

## What do the lights on my tracker device mean?

Motion Trackers have several possible states:

- Sleep
- Deep Sleep
- Initialising
- Advertising (waiting for connection)
- Connected

- Charging
- Charged
- No Battery
- Low Battery
- In Bootloader
- Updating Firmware

These states are reported to the user by using the LED present on the Motion Tracker.

Some of these states are related to the battery level (battery state), others are related to the Bluetooth connection (connection state). Therefore, the Motion Tracker is always in more than one state at a time - in a battery state and in a connection state. Nevertheless, there is only one LED on the Motion Tracker PCB and therefore a set of rules and priorities is used to define which state (the battery or the connection) is shown by the LED. Other states are related to the firmware update.

The following table shows the colour for each state:

State name	Battery state	Connection state	LED colour	Blinking
Deep sleep	N/A	N/A	None (off)	N/A
Sleep	N/A	N/A	None (off)	N/A
Initialising	N/A	N/A		No

Advertising (waiting for connection)		X		No
Connected		X		No
Charging	X			Yes
Charged	X			Yes
No battery	X			Yes
Low battery	X			Yes

X - state belongs to a connection state or battery state

N/A - not applicable (the state does not belong to a connection state or battery state)

## **Can the Digital Therapist provide a patient diagnosis?**

No. The Digital Therapist detects movement, the results analysis is performed by a Physical therapist, who concludes the progress/effectiveness of a certain physical therapy routine adjusted to the patient's diagnosis.

## **How do I set up the trackers?**

1. On the first use, the DT will ask you to connect the trackers to a USB cable to turn them on (they can be in a deep sleep state).
2. After this first step, the trackers will have a blue light once they are shaken.
3. If the trackers don't have enough battery, they will show a red light and if their battery is not enough to start a session the App will provide an alert.
4. To connect the trackers with the tablet (Bluetooth connection) the App will ask you to shake the trackers until they have a blue light and to click "connect".
5. The App guides you to the connection process until the trackers have a green light.
6. After step 5, it's time to place the trackers on the straps and on the body to start the calibration procedure.
7. The movement detection will be accurate if your trackers are in the correct position.
8. If something goes wrong, you can find the option to recalibrate, at the pause menu. You can repeat the calibration procedure anytime.
9. If the Bluetooth connection between the tablet and the trackers is lost during the session, the App will restore it, automatically.
10. When the session ends, if the trackers battery is low, the App will give you a warning.

## **Can I send a message to my Physical therapist?**

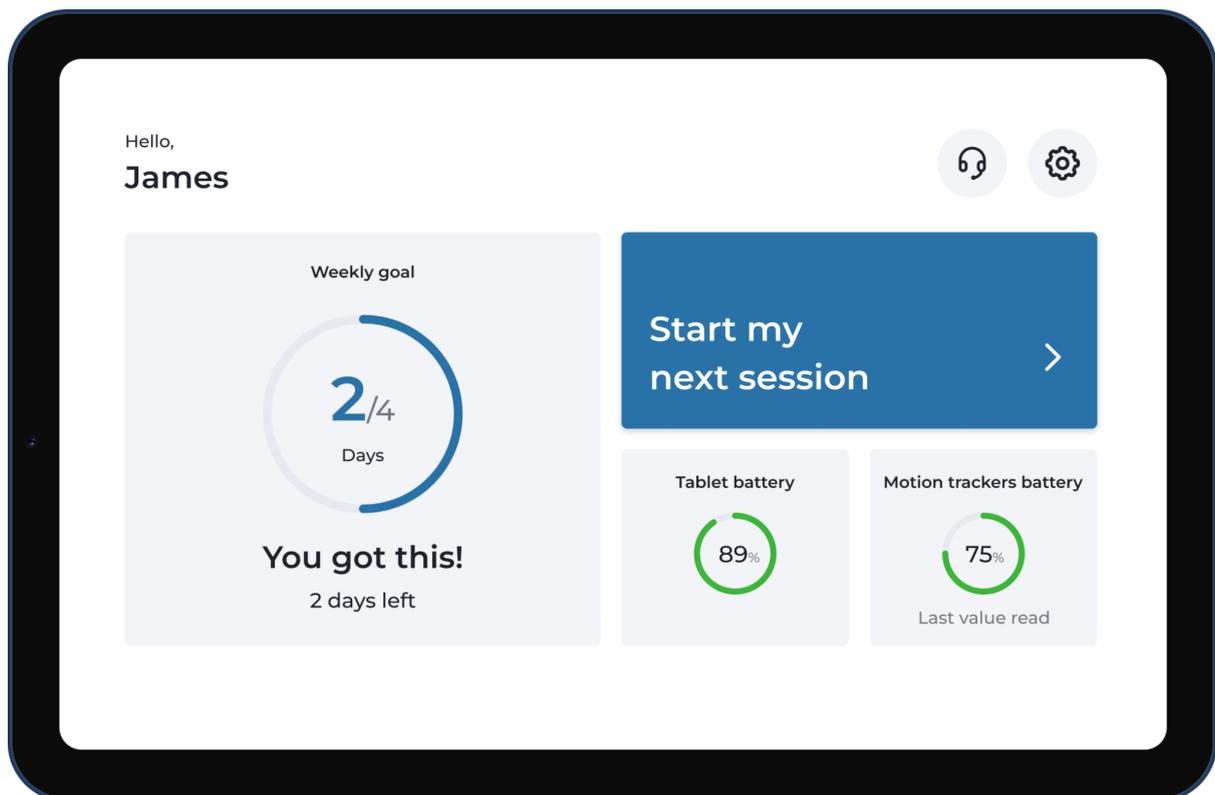
You can message your Physical therapist on the "Chat" tab on the Sword Health app. If you haven't already, download the app on your phone.

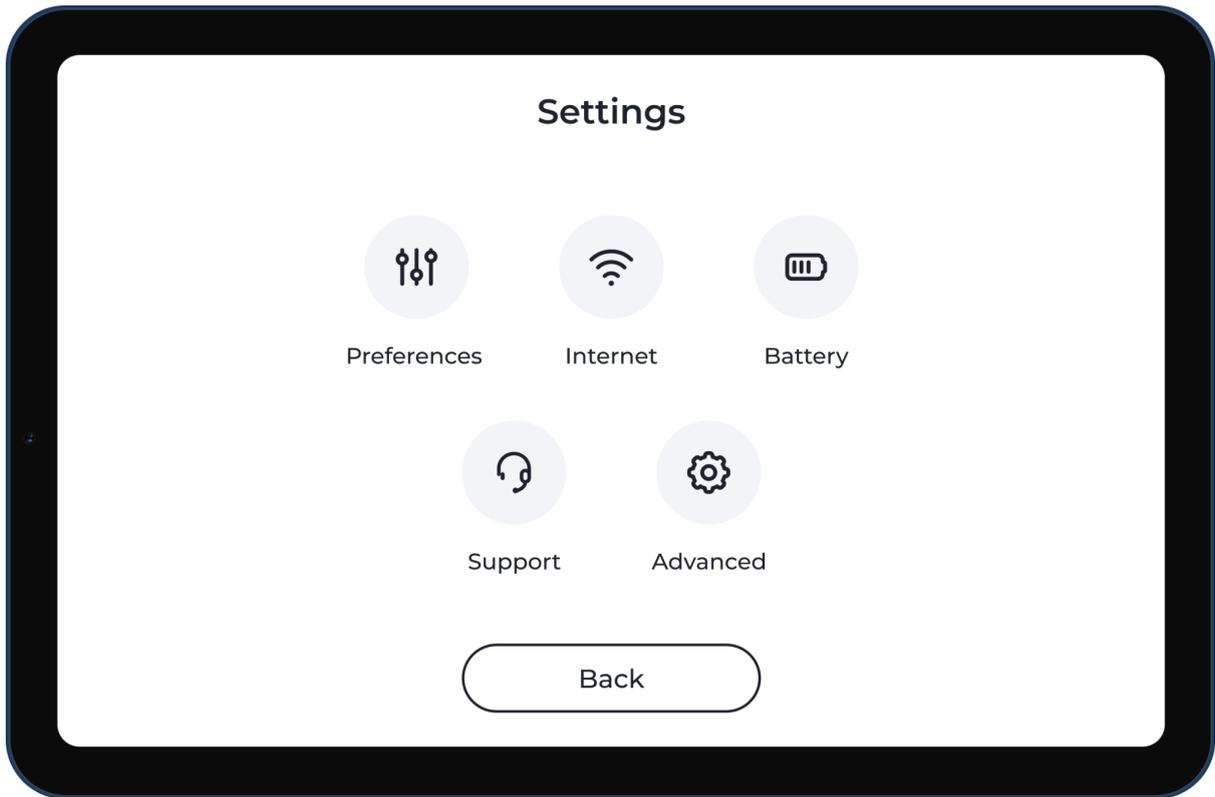
## Can I send a message to the Sword Health Support team?

You can send a message to the Sword Health Support Team using the DT.

Please confirm if you have the following button on the home screen. By tapping this button, you will be able to send a message directly to Sword Health Support team.

You can also find this option at settings - Support - Ask for Support.





### **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.

### **Should I recalibrate during an exercise session?**

Yes. If you need to move the straps or trackers you must recalibrate, otherwise it will affect the movement detection. Calibration procedure is required so the system “saves” the trackers position in your body. This procedure ensures an accurate movement detection and proper real time feedback.

### **Can I cancel a session?**

You have an option to leave the app before starting a session when you see their Overview.

You can choose to leave a session at any time, this option is available in the pause menu.

## **How long do I have to use the app for?**

The goal of the app is to guide you through an exercise program that can improve your quality of life and fitness levels, or tackle pain, discomfort or disability related with your bones, joints or tendons. Because everyone has different goals and needs, the length of your program can vary. Your Physical therapist will help you determine for 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. On average, users do 31 sessions in total, over 8-12 weeks.

## **What happens when my session ends?**

The DT sends your results to your Physical therapist. To do that, the DT needs a stable internet connection.

Keep your device on, near your Wi-Fi router when your session ends.

The DT will turn the device screen off, to save battery, when it's everything synced.

## **Who can see my data?**

Your data is shared with the Physical therapist 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 (movement detection done by the system)

## **How do you protect my data?**

We protect your data in several ways:

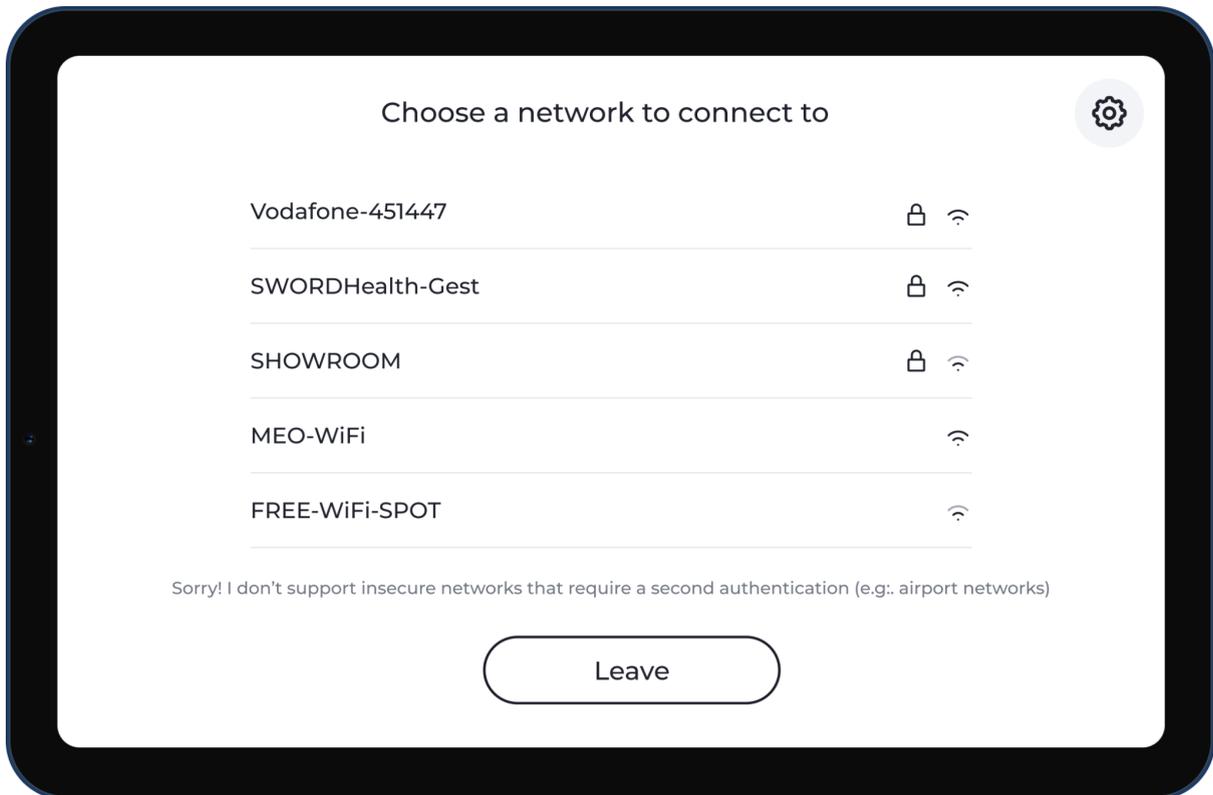
- Data is stored at rest and in backups using AES 256 encryption.
- Sword utilises the cloud provider's server-side encryption. Cloud provider manages keys.
- Access to data will be granted only to authorised users who are legally cleared to see data and on a 'need to know' basis.

## Who can I contact with questions about my data?

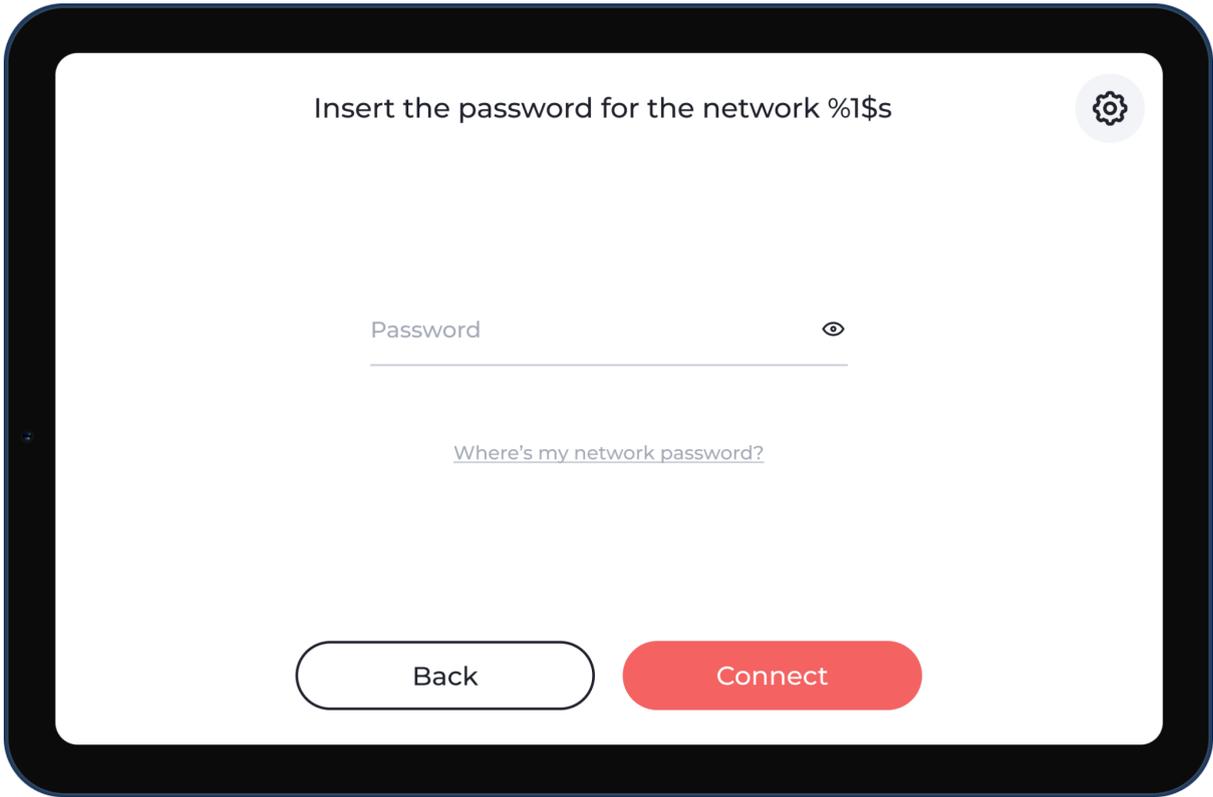
You should contact your Physical therapist initially. If you have any questions for Sword Health please contact our dedicated data protection officer by sending an email to [dpo@swordhealth.com](mailto:dpo@swordhealth.com).

## App setup

### Internet connection:

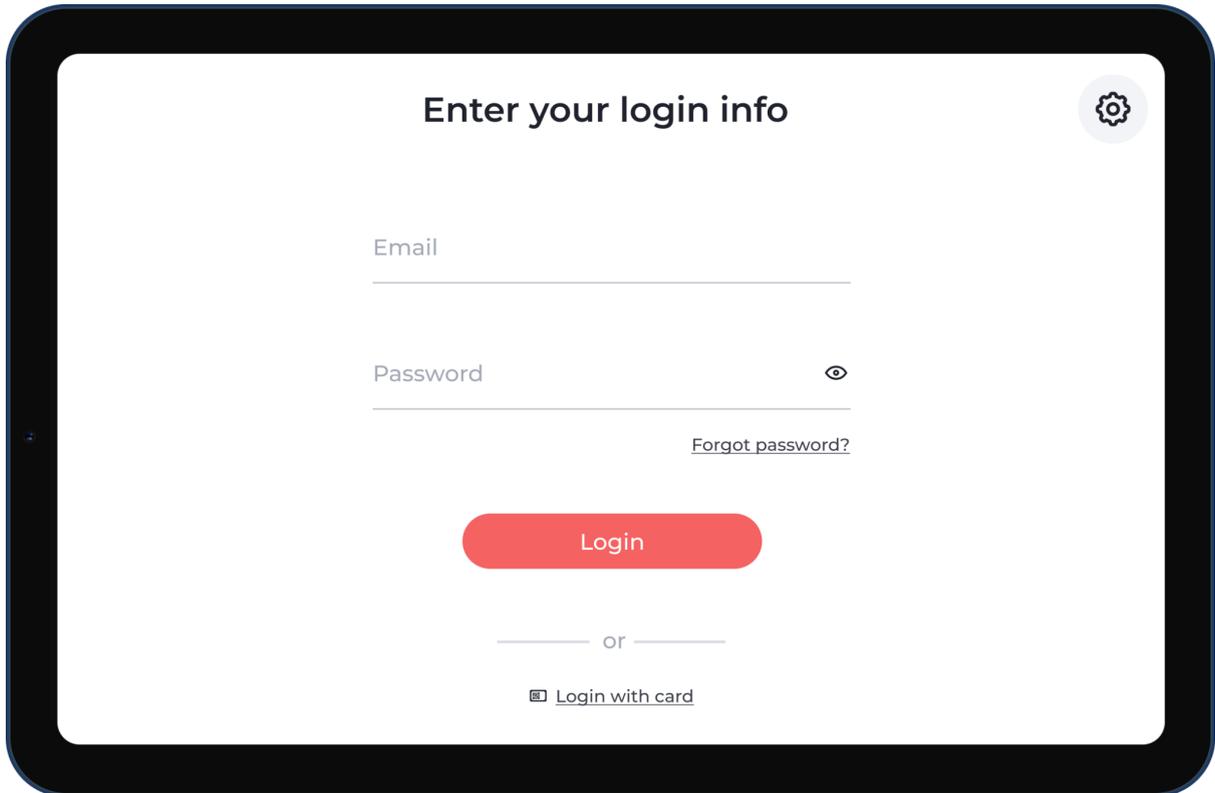


**Action:** Select your network between the list of networks your device is finding.



**Action:** Insert your network password and tap connect. The system will save it for future use.

## Login:

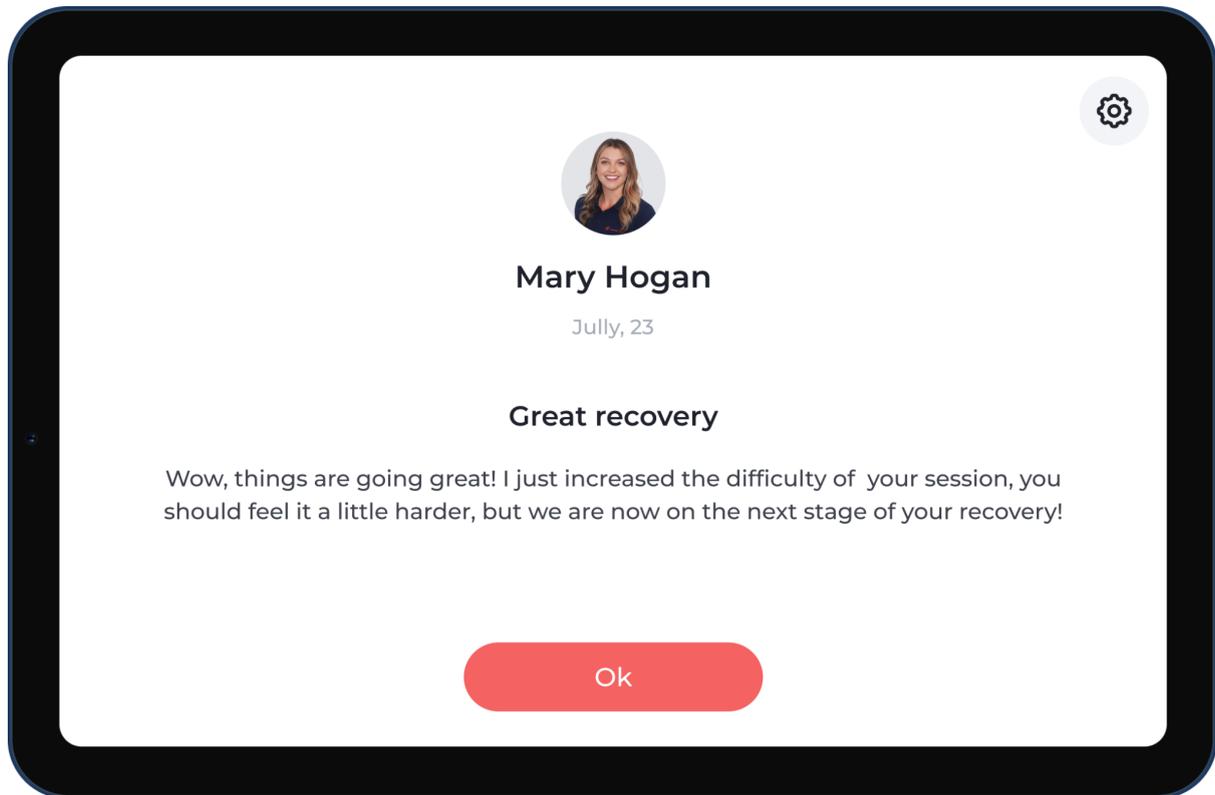


The screenshot shows a login interface with the following elements:

- Title:** "Enter your login info" centered at the top.
- Settings:** A gear icon in the top right corner.
- Email Field:** A text input field labeled "Email".
- Password Field:** A text input field labeled "Password" with an eye icon for toggling visibility.
- Forgot Password:** A link labeled "Forgot password?" located below the password field.
- Login Button:** A red rounded button labeled "Login".
- Separator:** A horizontal line with the word "or" in the center.
- Alternative Login:** A link labeled "Login with card" with a small icon to its left.

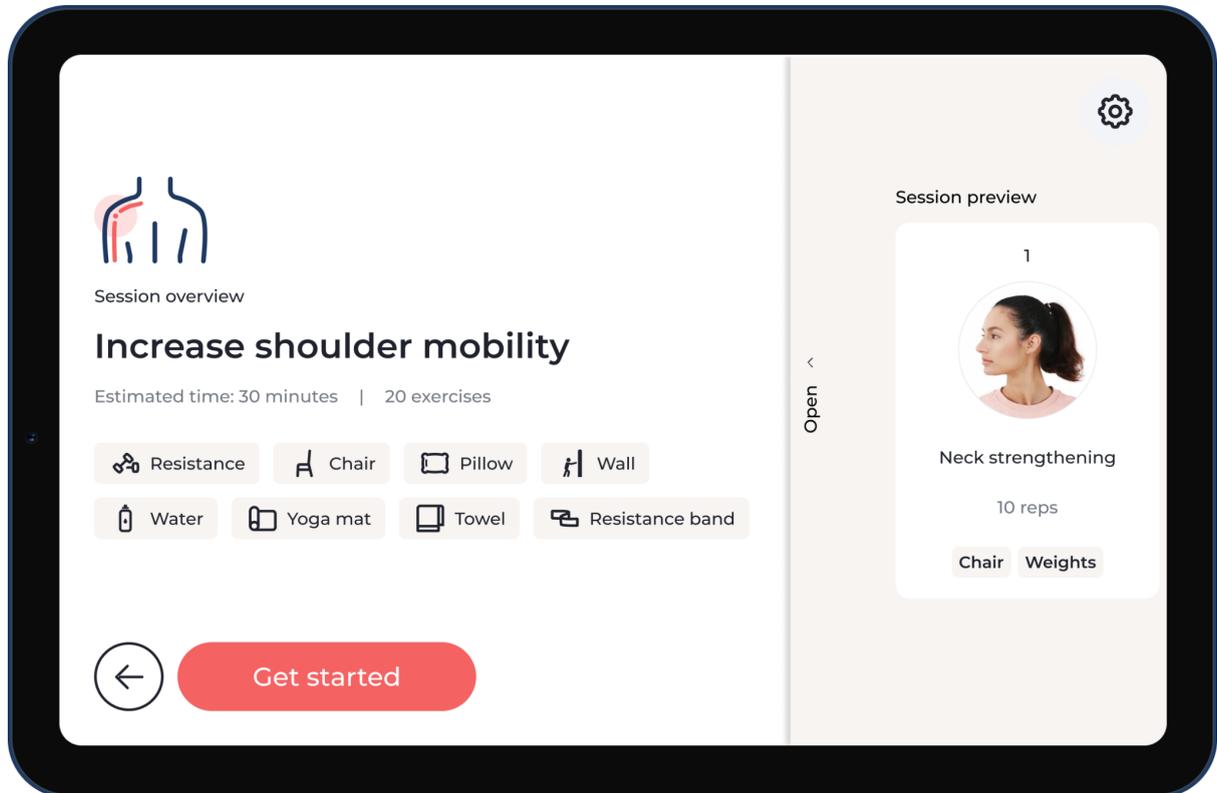
**Action:** Enter your email and password and click "Login". Use the email and password you choose while filling out the form to start your therapy with Sword.

## Read Physical therapist message



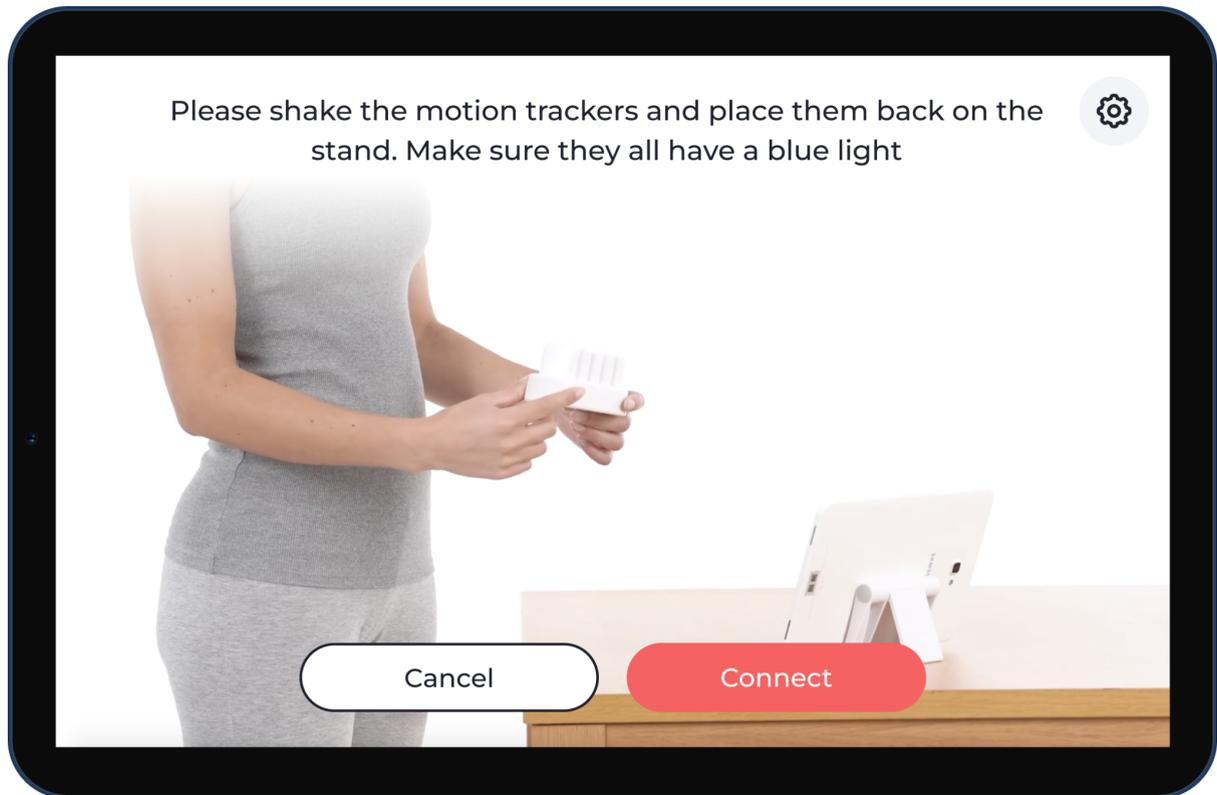
**Action:** Your Physical therapist can send you messages. If that's the case the Digital Therapist will show them to you before starting your next session.

## Start a session



**Action:** Before starting your session, the Digital Therapist shows you an overview of it with an estimated time, number of exercises and the material you will need to do your session.

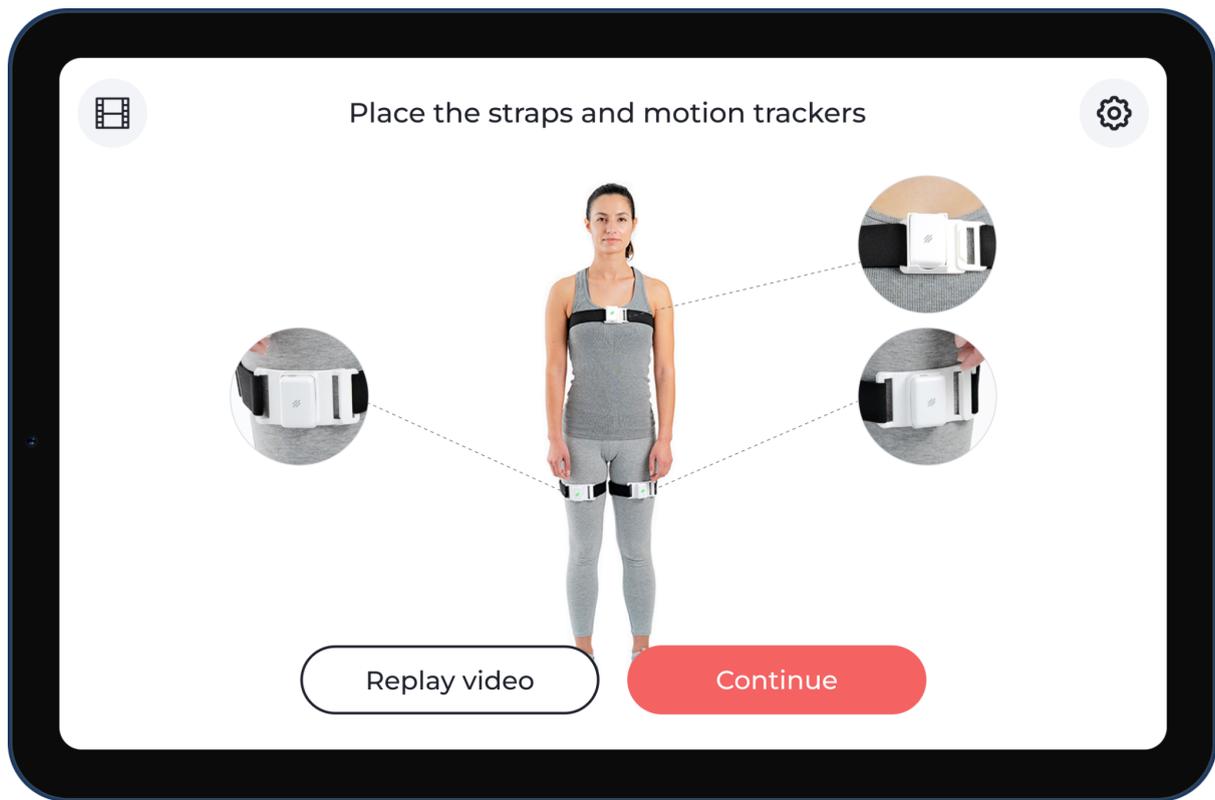
## Trackers connection



**Action:** You will need to shake the motion trackers so they will show a blue light and be able to start the connection with the tablet. If the trackers show a red light or yellow light, please place charge before use.

**Note:** The first time you start a session the trackers will be on a status called “deep sleep”. In this particular instance, you will need to place them into the charger and charge before use.

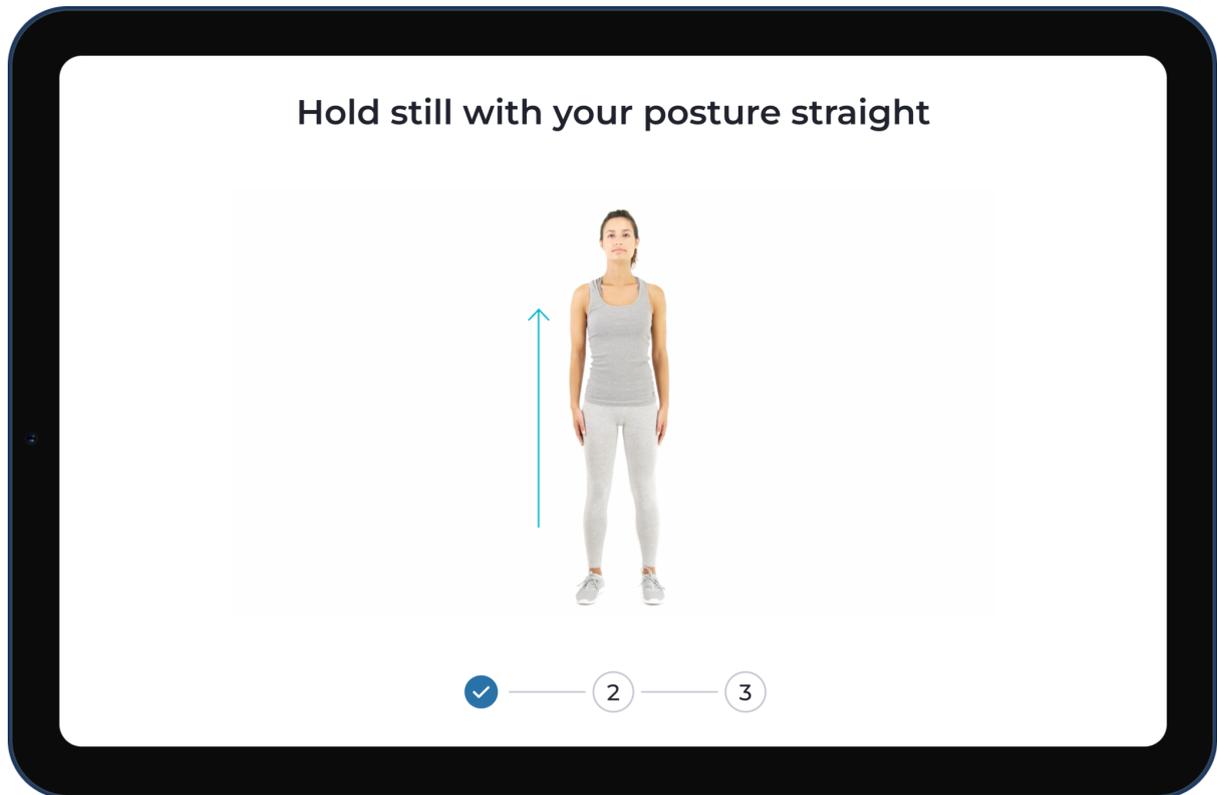
## Place the straps and trackers



**Action:** Before starting your first session. You will have a video explaining how to place the straps and trackers. You can re-watch the video whenever you want to, by tapping the button in the top left corner of this screen. After placing the straps and trackers correctly, click "I'm ready" to proceed.

**Note:** This is an example. You may have a different therapy to the example image above and may have a different image.

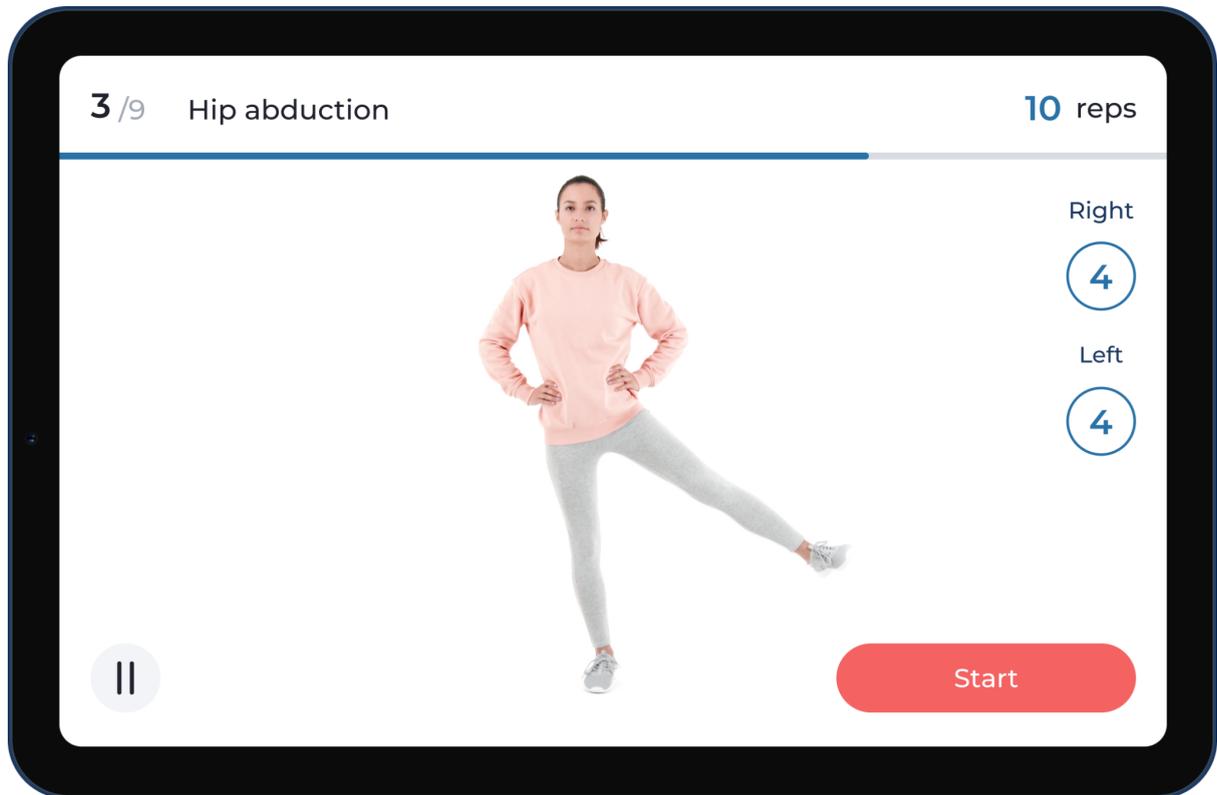
## Trackers Calibration



**Action:** The system will guide you through a step by step process of where to place the trackers on your body, these positions are “saved” so the system ensures accuracy on movement detection and corrects real time feedback during exercise execution.

Note: This is an example. Your setup can be different.

## Start an exercise

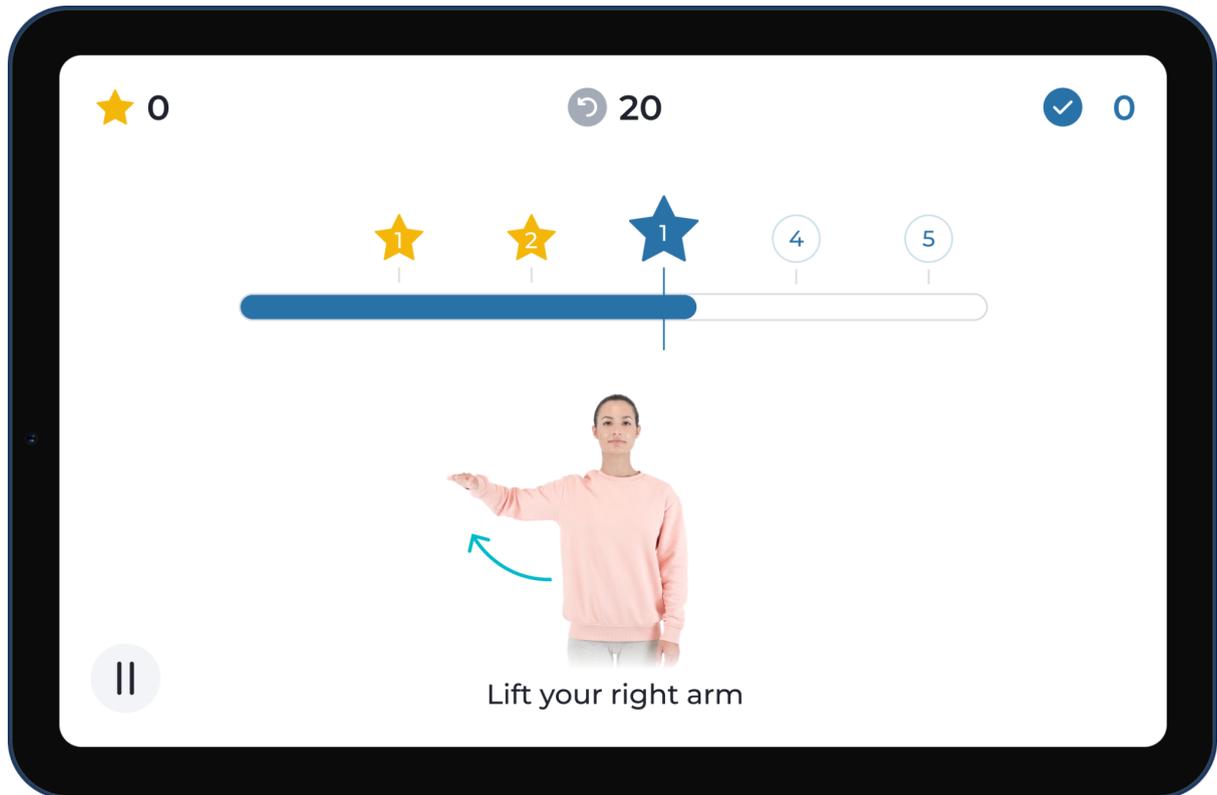


**Action:** Before each exercise you will see a video explaining how to perform the exercise. The exercise will then start by either clicking on the button “start” or by waiting for the video to end.

## Do an exercise

During your sessions, you will have different exercises, depending on your therapy.

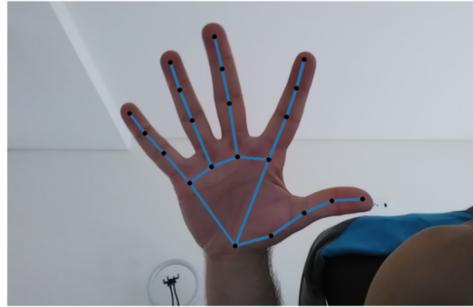
Here are some examples.



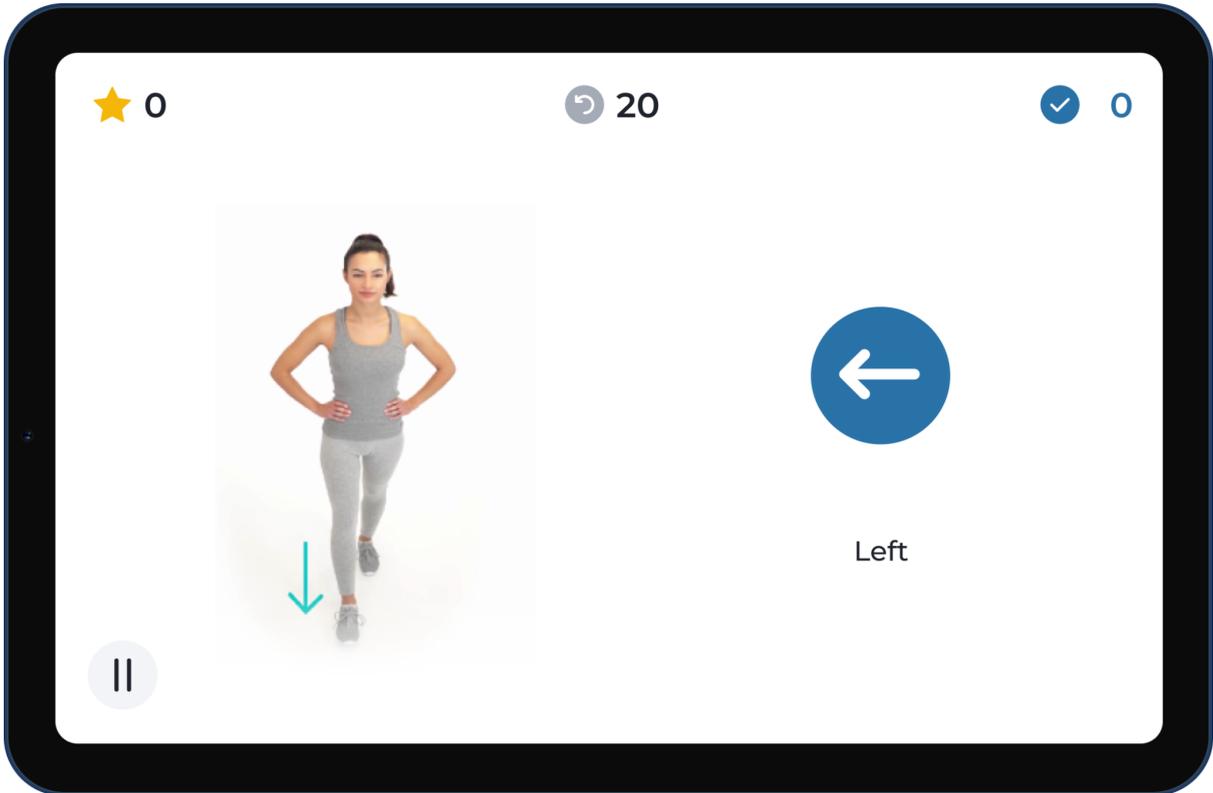
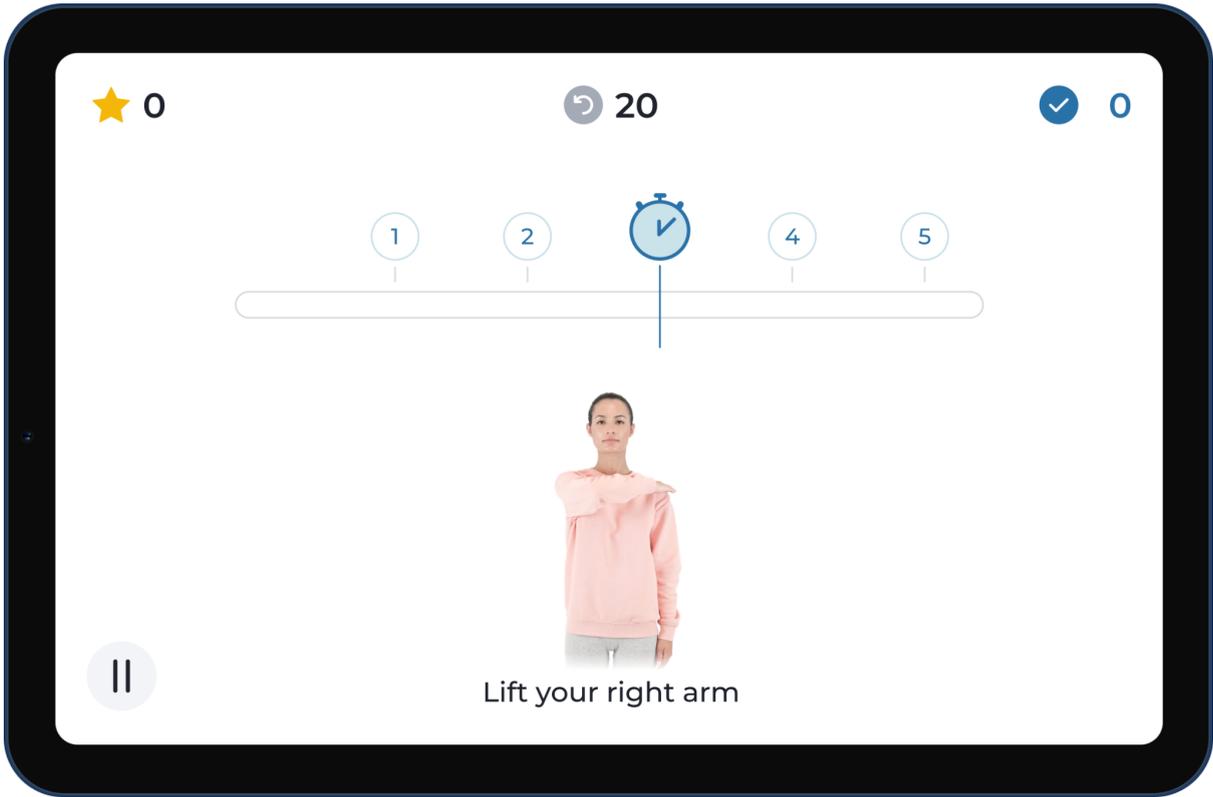
★ 5

↻ 1

✓ 1

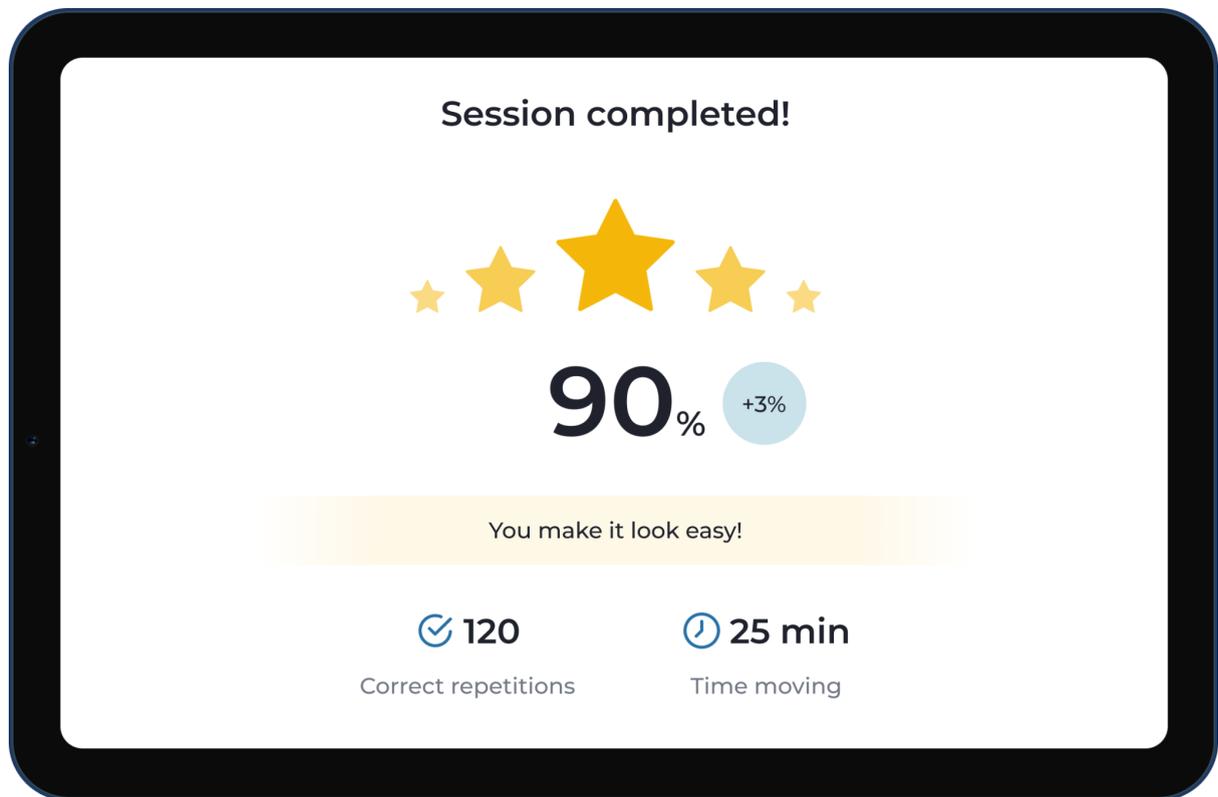


Move your fingers apart from each other



**Action:** Follow the Digital Therapist audio and written instructions to perform the exercises. The system detects your movement and provides real time feedback.

## End a session

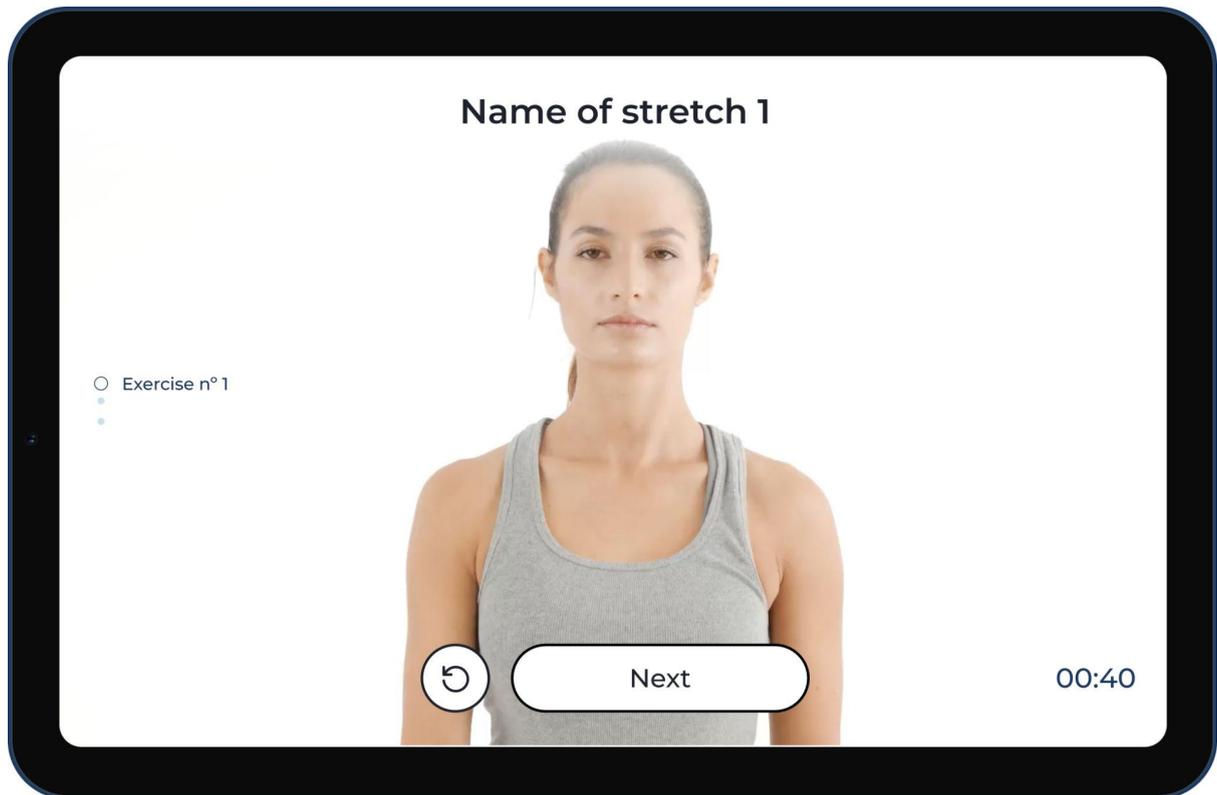


**Action:** Complete all of the exercises to end your session. Afterwards, you will have a screen showing your performance, including the number of correct repetitions and the time you spent moving.

## Warm ups & Stretches (recommended exercises)

Your Physical therapist can prescribe you optional exercises to perform during your sessions.

Here is an example of one of them.



**Action:** Follow the instructions and the movements you see in the video to do the exercises recommended by your therapist as warm-ups (before starting a session) and stretches (when your session ends).

## Rate your pain/fatigue level after each session

The screenshot shows a mobile application interface with a white background and a black border. At the top, the text "How did you feel during your session?" is centered, with a gear icon in the top right corner. Below this, the section "My pain today:" features six circular icons representing different pain levels. The third icon from the left is highlighted in orange and labeled "Moderate". The section "My fatigue today:" features six heart-shaped icons representing different fatigue levels. The third icon from the left is highlighted in yellow and labeled "Mild", while the sixth icon is labeled "The worst fatigue". At the bottom center, there is a red rounded rectangular button with the text "Continue".

**Action:** It is important to let your Physical therapist know your pain/fatigue level after each session, your prescription will be adjusted accordingly. Select the pain and fatigue rate that best describes your feeling during the session and click continue.

## Rate your experience

How would you rate your experience today? 



Satisfied

What should we improve in the future?

Movement detection    Tablet and/or motion trackers    Difficulty (too easy or hard)

Pacing (too fast or slow)    Physical Therapist    Other

Continue

How would you rate your experience today? 

What should we improve, specifically? 

Motion trackers connection    Battery    Equipment damage

Motion trackers accuracy    Ease of use    Wifi connection

Continue

Continue

**Action:** It is important to let your Physical therapist and Sword know how your experience was. Answer with the rating that best describes your satisfaction with the

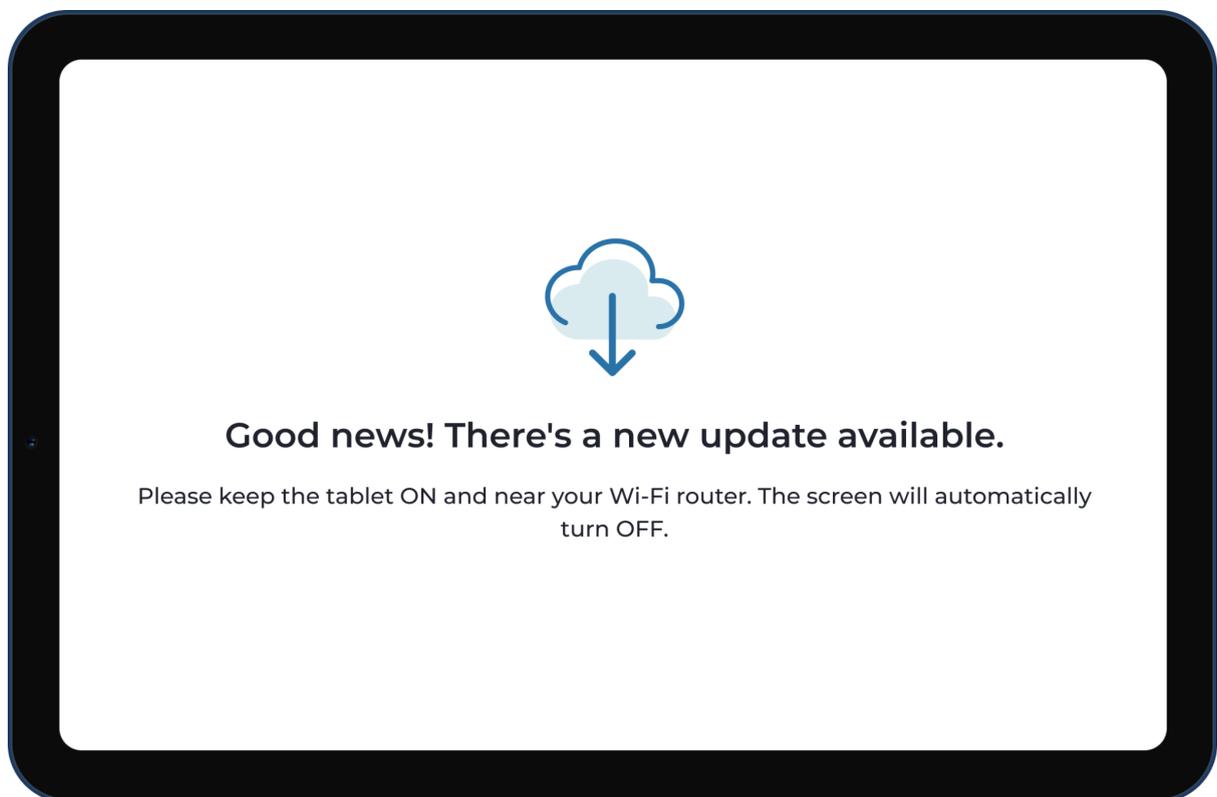
system on each day. If you rate your experience under 5, the system will ask you to select your reasons.

With your feedback Sword will improve the system to make your experience even better in the future.

## **App/trackers update**

You can receive an app / trackers update after ending a session.

If that is the case, you will see one of the following screens.



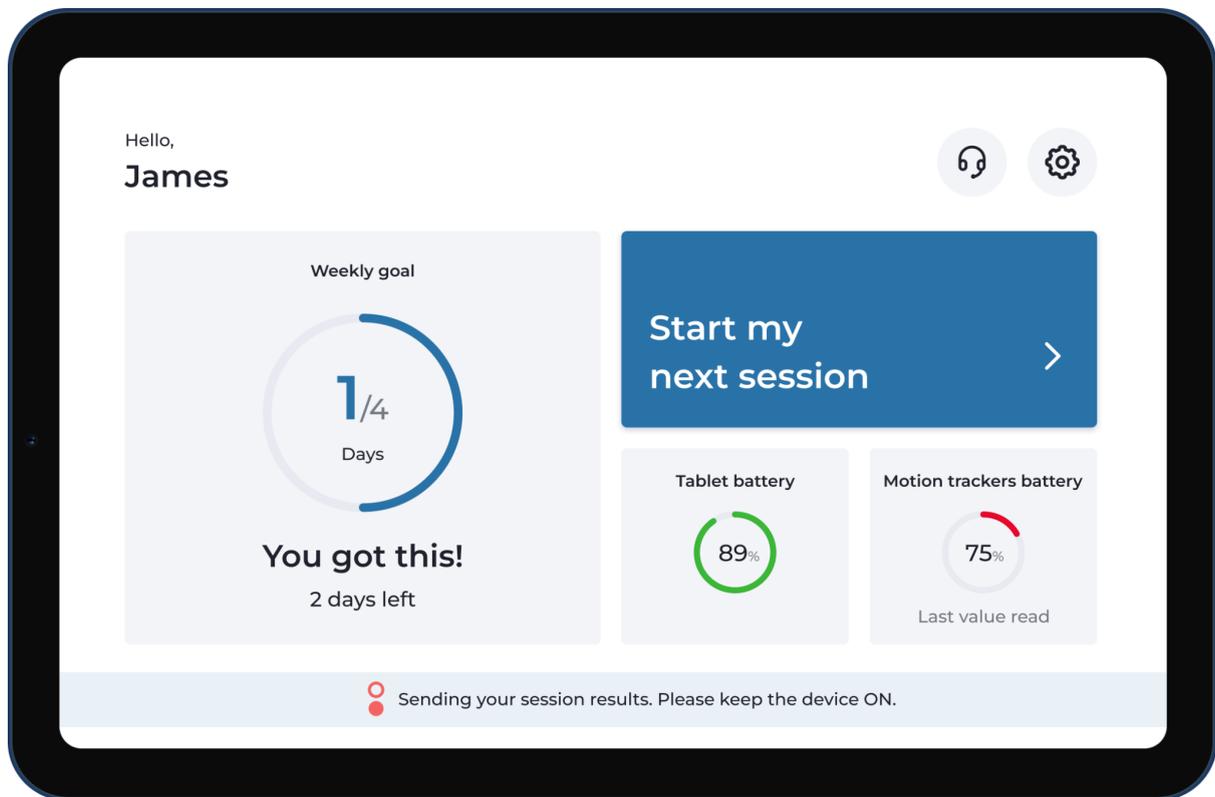


### **New update available!**

This update includes improvements to the motion trackers. This could take a few minutes, so please keep the tablet ON and near your WiFi router. The screen will automatically turn OFF.

**Action:** There is no action needed. The update will end automatically.

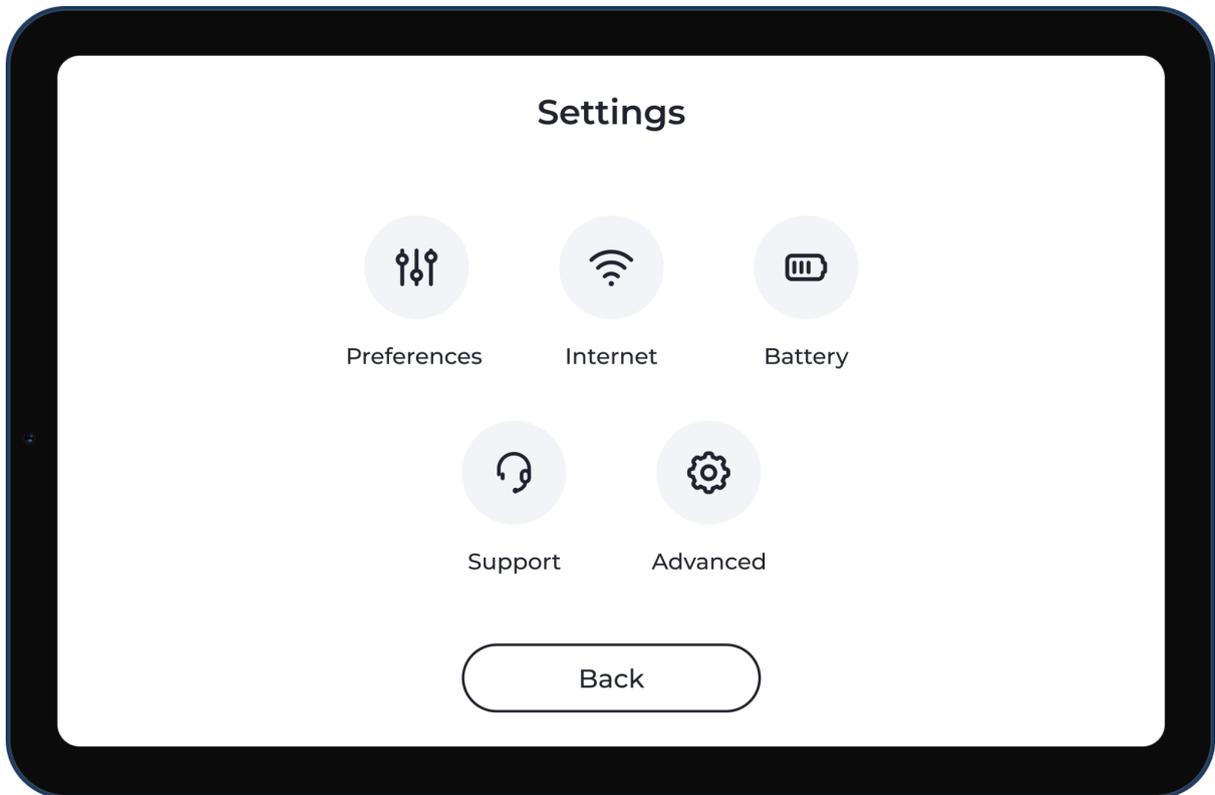
## Home screen



**Action:** While on the Home screen you can choose to start your next session. You will have information about your device battery level and the last battery value read from your motion trackers.

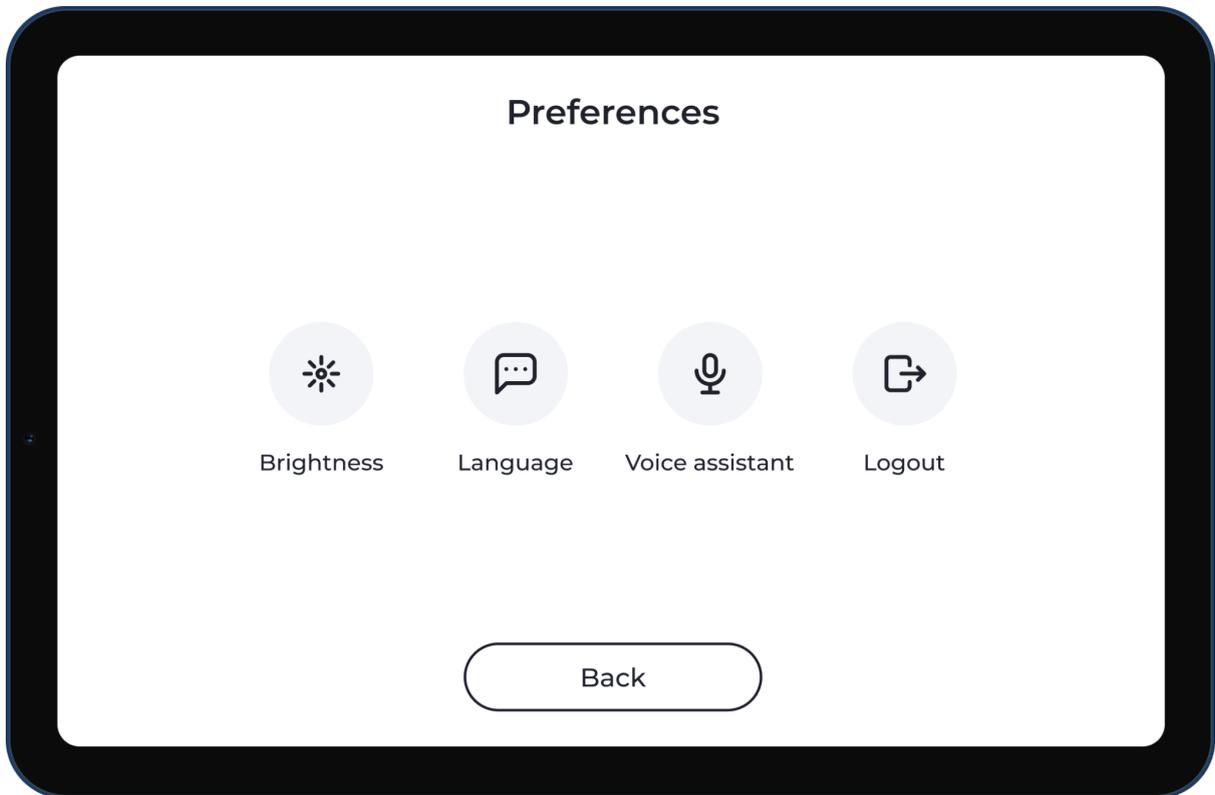
**Note:** If you see the warning at the bottom of the screen asking to keep the device ON it means that your sessions results are being synchronised so your Physical therapist can receive them and update your prescription based on this information.

## Settings



**Action:** By clicking on the settings button (upper right corner on the screen) you will have access to this menu where you can find useful functionalities.

## Logout



**Action:** You can choose to Logout whenever you want by opening the menu “Preferences” in the Digital Therapist settings. Click the option “Logout” and the system will delete your login information.

## View the results from your sessions

You can access your session results on the Sword Health app. If you haven't already, download the app on your phone.

## Review how many sessions you have completed

Information about how many sessions you have completed can be found on the Sword Health app.

## Terms and conditions

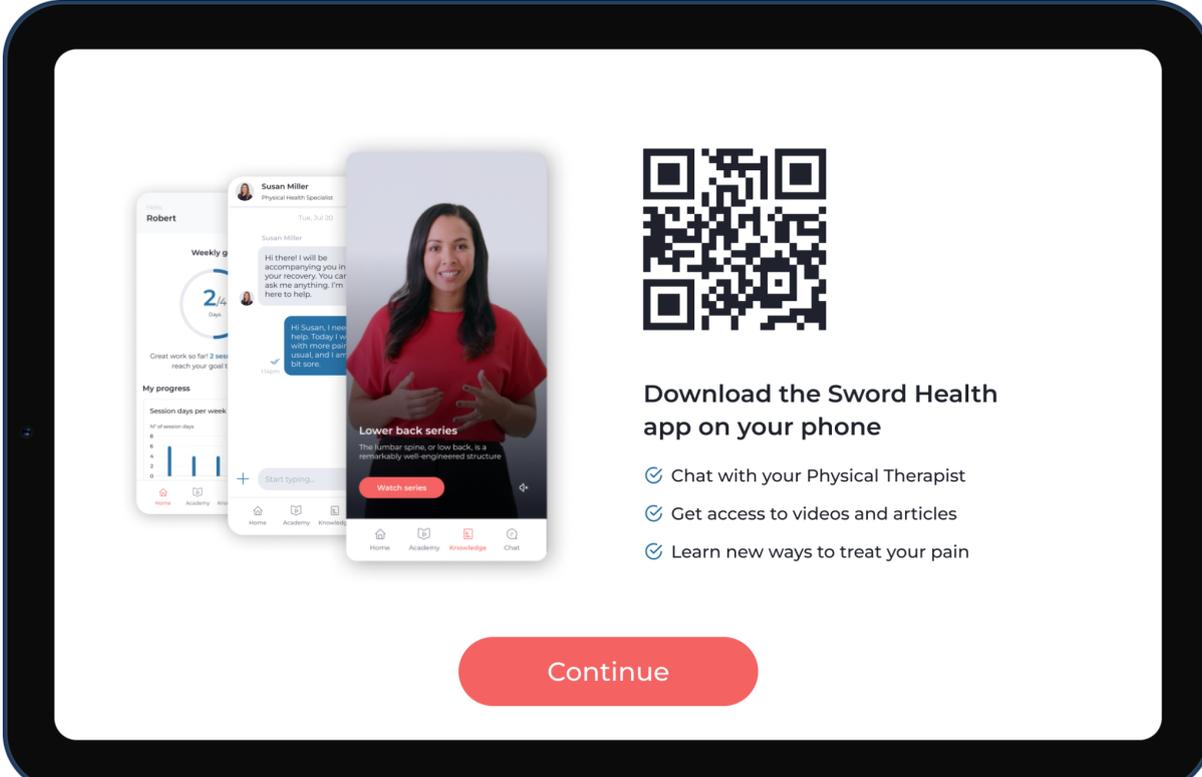
The terms and conditions for the use of the Digital Therapist are agreed during the onboarding process to the rehabilitation program.

## Troubleshooting

### How do I install the Sword Health app in my phone?

1. Open the store (iOS: App store; Android: Play store)
2. Search the Sword Health app in the store
3. Click on the install button

You can also scan the following QR with your phone code and install the App:



The image shows a promotional graphic for the Sword Health app. On the left, there are three overlapping smartphone screens. The top screen shows a chat interface with a physical therapist named Susan Miller. The middle screen shows a video series titled 'Lower back series' featuring a woman in a red shirt. The bottom screen shows a progress chart. To the right of the screens is a large QR code. Below the QR code, the text reads 'Download the Sword Health app on your phone'. Underneath this text are three bullet points: 'Chat with your Physical Therapist', 'Get access to videos and articles', and 'Learn new ways to treat your pain'. At the bottom center of the graphic is a red button with the word 'Continue' in white text.

### I can't see the results from my last session in the Sword Health app

To ensure your session data is synchronised, follow the instructions and keep your device ON and connected to the wifi after ending your session on the Digital Therapist.

To make sure that everything is synchronised, you can choose the option to Sync data on the menu Support within the Digital Therapist settings.

## **I needed to change the placement of the trackers during a session**

If you need to change the trackers placement on your body at the middle of a session you will need to recalibrate. This option is available on the pause menu during exercise execution.

Calibrating the system “saves” the trackers position on your body and ensures precision in the movement detection, providing you with the most accurate real time feedback.

## **I can't perform an exercise**

Please contact your Physical therapist. Your Physical therapist will update your prescription and/or give you tips to perform the exercise correctly.

## **An app update is taking too long**

Please confirm if you have a stable internet connection.

You can do a test to confirm it by opening the menu Wifi in the Digital Therapist settings and choosing the option Internet Speed Test.

If you have a stable internet connection but the update does not end, please contact Sword Health Support team.

If you don't have a stable internet connection in your home, please contact the Sword Health Support team.

## **My app keeps freezing**

Please contact Sword Health Support team.

## **My app shut down mid-session**

Please contact Sword Health Support team.

## **My tablet/trackers discharge too quickly**

Please contact the Sword Health Support team. If your hardware is damaged, Sword Health will replace it.

## **Appendix 1 - Camera Exercises**

Your Physical therapist can include camera-based exercises on your session prescription.

The system will guide you through a flow prior to starting, to show you how to position yourself within the camera frame.

When performing exercises with this type of movement detection technology, there is no need to have the motion trackers in your body.

To perform camera based exercises, you must keep the tablet in the stand (included on your kit) to ensure proper positioning.



©2022 Sword Health. All Rights Reserved

[help@swordhealth.com](mailto:help@swordhealth.com)