

Konectom

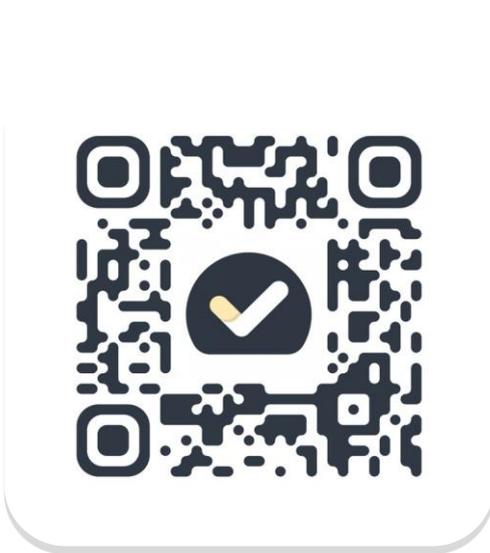
Instructions for use

Let's start

Depending on your study, you will be asked to use Konectom on your personal phone or your study phone.

How to download the app on my personal phone?

Use this QR code



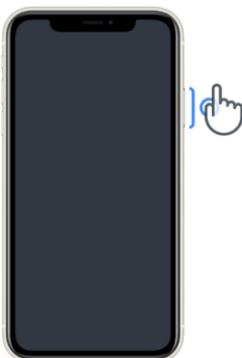
Or directly from the store

- 1 Open the Play Store (Android) or App Store (iOS)
- 2 Find Konectom
- 3 Then Press «Install» (Android) or «Get» (IOS)
- 4 If prompted, log in to the App Store or Play Store to complete the

How to use my study dedicated iPhone?

To unlock the phone

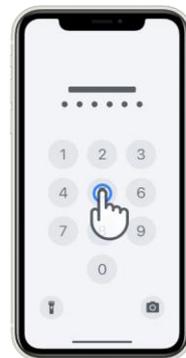
- 1 Press the side button



- 2 Swipe up from the bottom of the



- 3 Enter the passcode



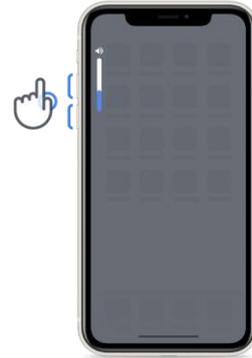
To launch the app
tap the icon



To lock the phone
press the side button



To adjust volume
press the left side buttons



Make sure to charge the iPhone regularly and have enough battery before performing the activities.



What is Konectom?

Konectom is a smartphone app that contains multiple activities that you can do by yourself.

Why use Konectom?

Mobile technology has great potential to improve the way Healthcare Professionals assess neurological functions and provide care. By using Konectom, you will help Healthcare Professionals and researchers to evaluate this potential assessment. Thanks for using the app!

Warnings and Precautions

- 1 Perform the activities in a safe and quiet environment with no distractions.
- 2 Make sure you have enough space, choose a level surface free from obstructions to avoid unnecessary fatigue or risk of injury, during the Balance & U-Turn and Daily Walk activities.
- 3 If using a running belt for any tests, ensure that the phone is securely placed on your lower back before starting.
- 4 Please note that before starting the Daily Walk activity, access to Smartphone GPS must be authorized.
- 5 If you feel any discomfort while performing the tests, please stop the activity immediately and consult the clinical study doctor.
- 6 Don't use Konectom while doing other activities (e.g., driving, talking with others) or in a noisy environment (e.g., trains, restaurants).
- 7 Do not perform the activities before you understand the instructions.
- 8 Do not ask family or friends to try the app and perform the Konectom activities, this could impact the data collected.
- 9 Konectom does not provide any recommendations or conclusions related to diagnosis or treatment.

Konectom Activities

Depending on your study protocol, you might not be asked to perform all below activities:



Symbols & Numbers

Measures your ability to process information. You are asked to match, as fast as possible, symbols and numbers according to the information provided in the activity.



Pinch Balloons

Measures your ability to grip small objects with your fingers. You need to pinch as many balloons as possible for 30 seconds.



Draw a Shape

Measures your ability to move your index finger quickly and accurately. You are asked to draw a set of shapes on your smartphone as quickly and accurately as possible.



Balance & U-Turn

Measures your ability to balance and make U-turns. For balance, you are asked to stand still for 30 seconds. For the U-turn, you are asked to walk 5 steps and make a complete U-turn at least 5 times.



Daily Walk

Measures your ability to walk for a long time. You are asked to walk outdoors with your smartphone as fast and as far as possible for 6 minutes.



Surveys

You are asked to complete surveys and questionnaires to understand your perception of your health.

Konectom™

Konectom™ is intended to be used as a self-assessment tool to objectively quantify motor and cognitive functions, and their impairments associated with Multiple Sclerosis (MS).

Konectom does not provide any recommendations or conclusions related to diagnosis or treatment.

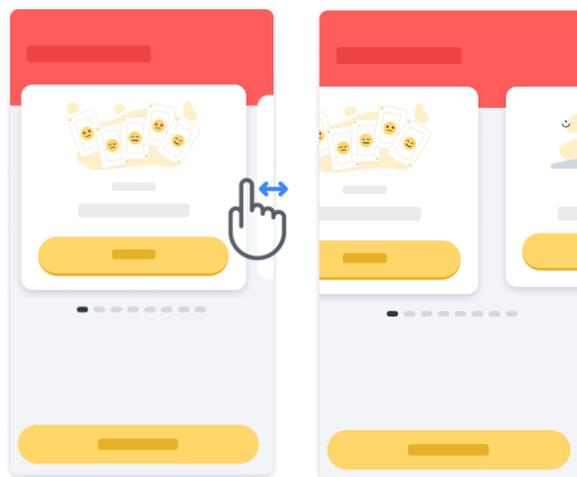
Operational Use

1 Demo Mode

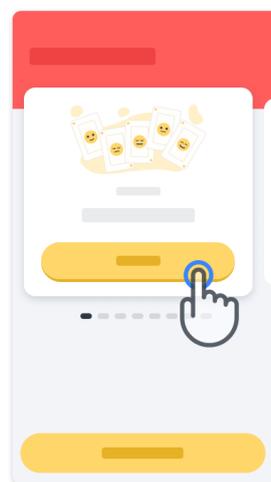
Demo Mode can be used to demonstrate the use of Konectom without collecting any data and with no limitation in the number of tests executed. It is accessible while the user is not yet logged into Konectom.

This mode could be used by the Healthcare Professional team to demonstrate how to use Konectom.

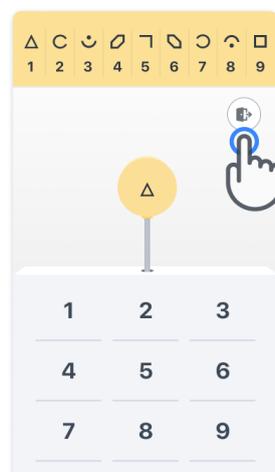
To start an activity, swipe left or right, to choose one of the proposed activities.



Then click on the yellow start button to start it.



You will be guided through an activity instructions and practice run before performing the activity by itself. The activity can be left at any time using the exit button  .

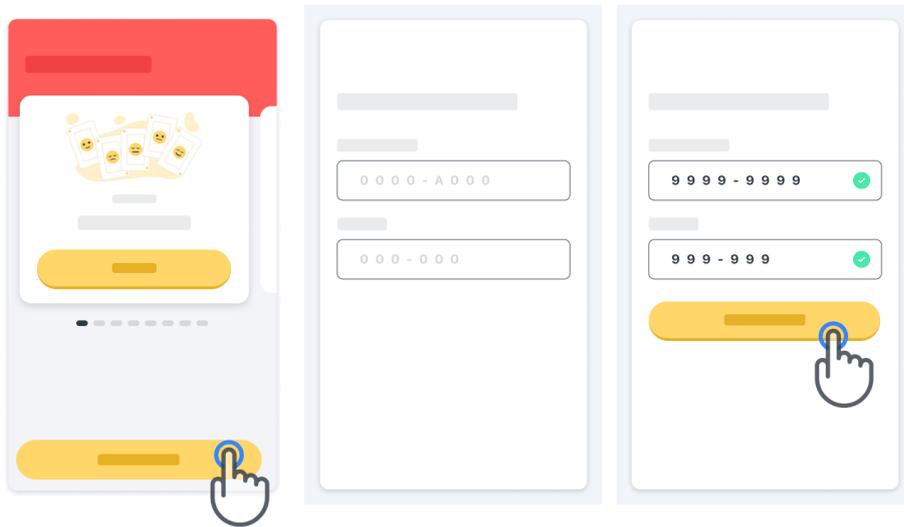


2

Log In

From the Demo Mode, click the yellow Log In button at the bottom of the screen.

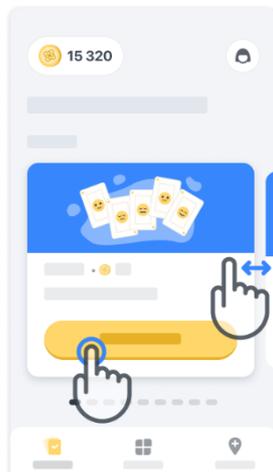
Please use the patient ID and activation code provided by the Healthcare Professional to log in. Your credentials are located on the printed Credential Card, provided to you by the Healthcare Professional during your onboarding to the Konectom application. You can also find on this card your study investigator contact.



3

Using the homepage

The activity carousel in the homepage can be used to select the activity to perform by swiping left or right. Launch the activity with the start button of the activity card.

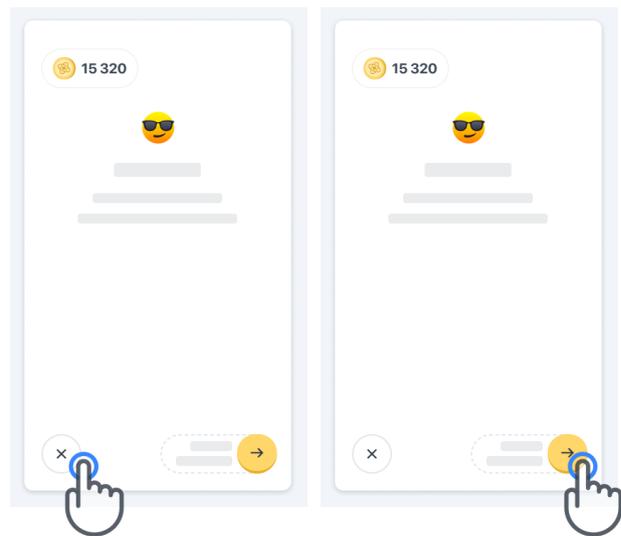


4

Perform the activity

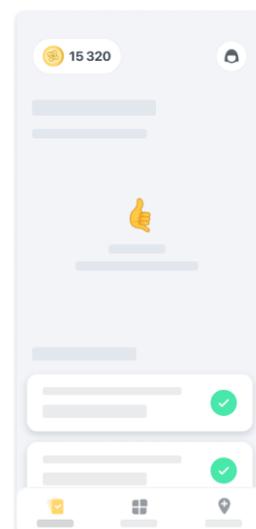
The first time you select the activity, you will go through the activity's instructions and will be offered the possibility to perform an activity step by step practice run before executing the real activity.

Once the activity is performed, you can choose to go back to the homepage  or start another activity  .



Please note that the step by step practice is available in the app for the first executions of the activities. To be able to perform the practice another time, the user is required to log out and log in using the same provided credentials.

Once the activities are completed, they will be listed in the «Completed» section of the homepage.

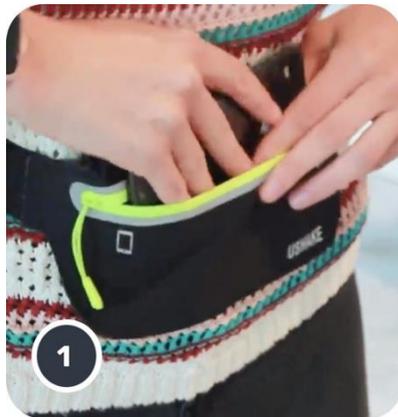


5

Practice Balance & U-Turn and Daily Walk activities

During the Balance & U-Turn and Daily Walk activities, you can place the mobile phone in a running belt positioned in the center of your lower back or in your pocket if you don't have a running belt.

You can use an assistive and/or orthotic device as needed.



First, put the running belt around your waist, place the smartphone in and close the zipper.

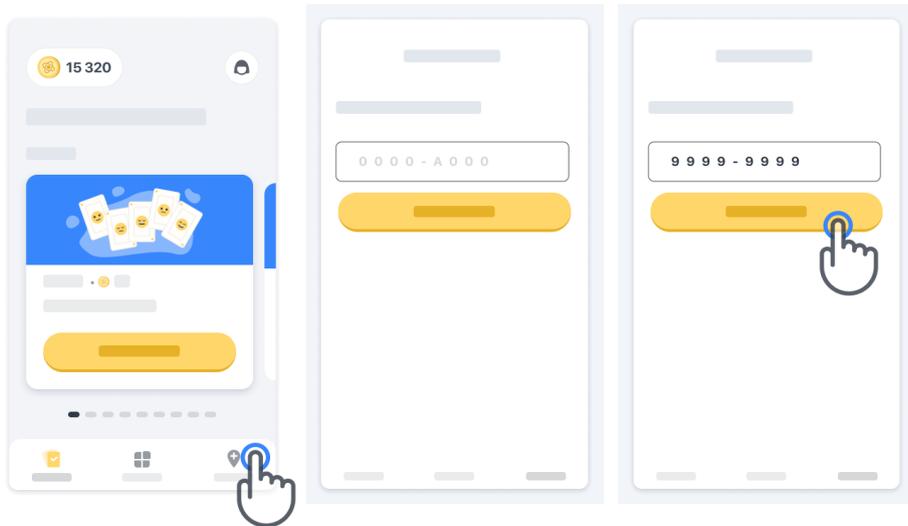


Then slide the running belt around your waist so that the smartphone is centered in your lower back.

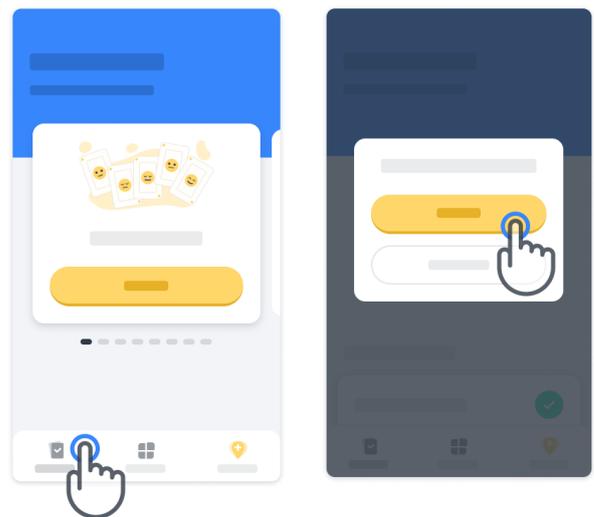
6 Access to the In-Clinic mode

The In-Clinic mode is only available for Healthcare Professionals.

Healthcare Professionals can access the In-Clinic mode in the menu bar, from the homepage. A specific code is required to log in.



To exit the In-Clinic mode, simply select another item from the menu bar.

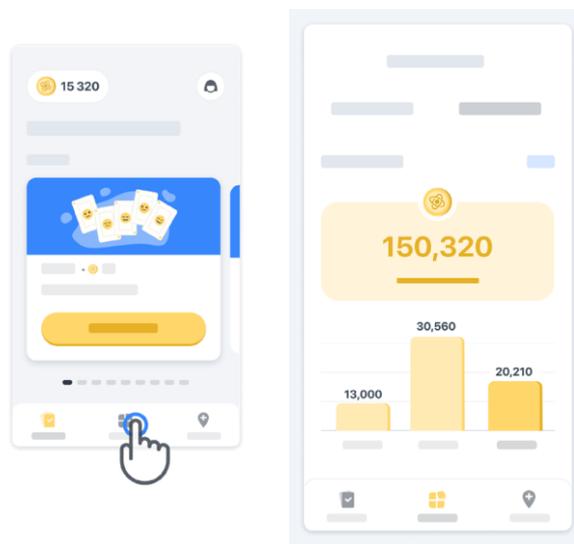


7

Understand points

On the top left of the homepage you will see a point counter, those points are called *science points*.

Every time you complete an activity, you will receive some science points. They represent your contribution to scientific research thanks to your participation in the study. The science points are not based on your performance but only your ability to complete the test.



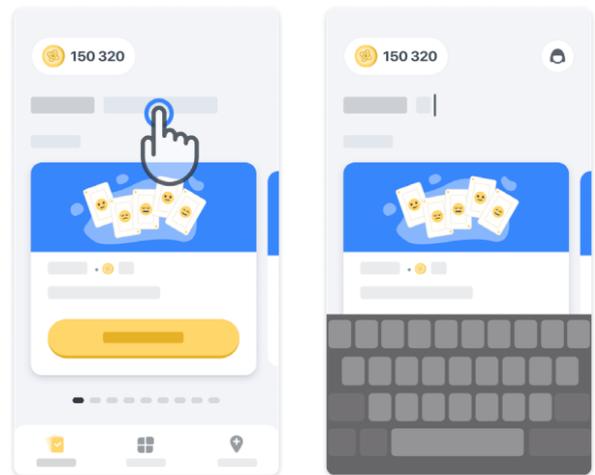
8

Personalize your app

You can personalize your app with your nickname by clicking on «Your nickname» on the homepage. You could change it at any time in your Profile page.

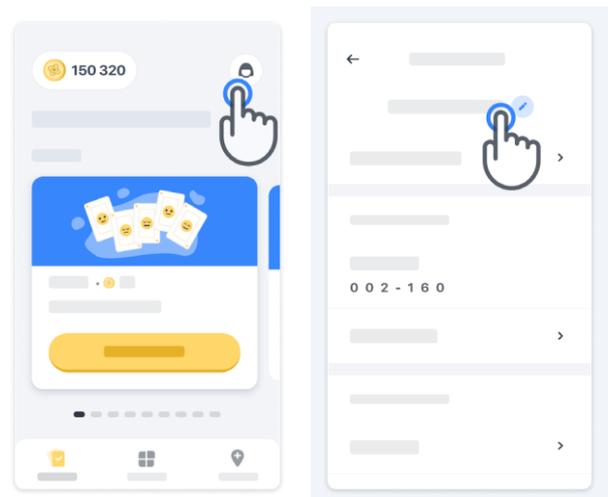
Note: This information is stored only on your smartphone and we cannot access this information.

Click on «Your nickname» placeholder to edit it, then click anywhere on the homepage to save and close the keyboard.



At any time during the study you can edit it by clicking on the Profile icon

 then on the edit button .

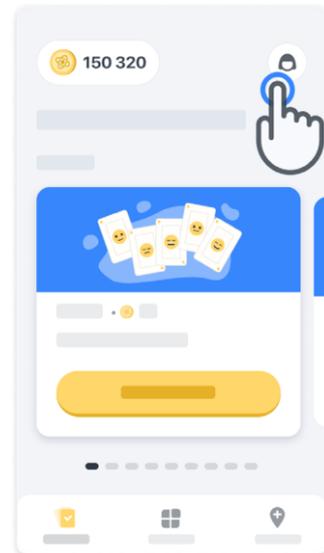


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Get answers to your questions

During the study you could have questions about Konectom or about a technical issue. Please note that you can find a lot of information in the Help section in your Profile.

You can access to the Help section by clicking on the Profile icon  .



If you would like to report any technical issues or feedback regarding the app you can use the form in the “Contact Us” (This feature is not available to all users). If this section is not available for you, please contact your study coordinator.

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Remain connected

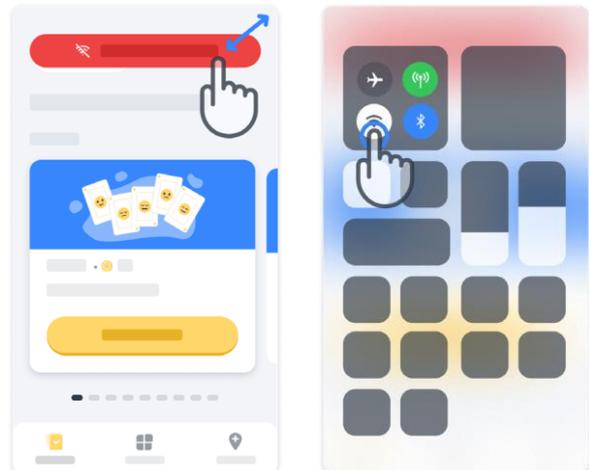
Konectom data is transferred automatically to the server when internet connection is available.

You can complete Konectom activities offline but we highly recommend to remain online.

If a red banner is displayed on the top of your screen, it means you need to connect your mobile phone to the internet.

First, check if the flight mode isn't active  and if the Wi-Fi mode is active .

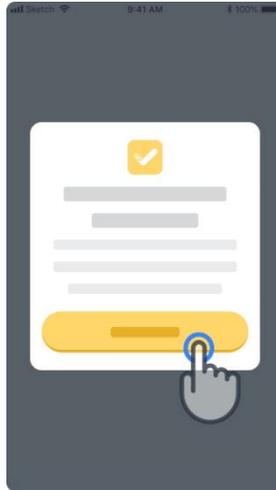
In case your Wi-Fi connection does not work properly, please make sure cellular connection is ON.



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Keep the application up to date

Sometimes a newer version of the application might be ready for you. When you see this screen, make sure to have a good internet connection and update your application.

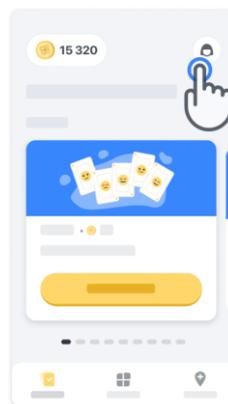


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Log out

The user can log out of Konectom by going into the Profile section. To access the Profile section, click the Profile button located in the top right part of the homepage. Once the user is in the Profile section, scroll down the page to see the Log Out button.

Please note that, the Log Out button is not available for all users.



Hardware Requirements

Konectom App

Konectom mobile application is to be installed on a smartphone that has Internet/Wi-Fi access (required for downloading and updating the app, and for uploading data to the server only), sufficient available storage, and has an adequate power supply for usage.

Konectom mobile application is to be used on the following commercially available smartphones:

- iPhone with at least iOS 13 version or above
- Smartphone with Android at least version 8.0 or above.
- Smartphone hardware including IMU (inertial measurement unit (IMU) and GPS (Global Positioning System) sensors, as originally configured Off The Shelf.

Contact

Legal Manufacturer

Biogen Digital Health, Inc.
225 Binney St, Cambridge,
MA 02142, USA

If you are using Konectom in the European Union Memberstate countries, please note that any serious incident that has occurred in relation to the device should be reported to the manufacturer or European Authorised Representative and the competent authority of the Member State in which the user and/or patient is established.

If you are using Konectom in Switzerland, please note that any serious incident that has occurred in relation to the device should be reported to the manufacturer or Swiss Authorised Representative and the competent authority in Switzerland.

Symbols

If you are using Konectom outside of EU, Switzerland or United Kingdom please refer to the below labelling elements:



Consult electronic Instructions for Use



Manufacturer information



Date of Manufacture
Software release date

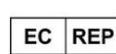
If you are using Konectom in the European Union Memberstate countries, Switzerland or United Kingdom please refer to the below labelling elements:



Consult electronic Instructions for Use



Manufacturer information



European Authorised Representative information



Swiss Authorised Representative Information



Date of Manufacture
Software release date



CE Mark



Unique Device Identifier



Medical Device within the European Union



European Union Importer
MedEnvoy Global B.V.
Prinses Margrietplantsoen 33
Suite 123
2595 AM The Hague
The Netherlands



Swiss Importer
MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

Biogen Digital Health, Inc (the Licensor) is the Legal Manufacturer of Konectom (the Software). The Software is a CE marked medical device. The Licensor has appointed MedEnvoy Global B.V. (the Licensee) as an importer of the Software, in accordance with the Medical Device Regulation (EU) 2017/745 and any other applicable laws and regulations. The Licensor has granted a license to the Licensee to make available the Software in the context of clinical trials only. Under this License, the Licensee is entitled to sublicense the Software for free to patients enrolled in clinical trials where the Software is being used, in accordance with its intended use. Nothing in this License shall be construed to assign or transfer any ownership or other intellectual property rights from the Licensor to the Licensee.

Thank You!

for being part of the Konectom Adventure

