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| Document Number and Title | REC-001-004 Instructions for Use — Ayla v2.0.0 |
| Information Classification | Public |



Instructions for Use

Ayla

your CST Assistant

Manufactured by Brainplus UK Limited

Version 2.0.0

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Instructions Version History

| Version | Description of Changes | Date |
|----------------|---|--------------|
| 1 | Initial Version (Brain+ A/S) | 26-Sept-2024 |
| 2 | <p>Rebranded from Brain+ A/S to Brainplus UK Limited and updated product references to Ayla throughout</p> <p>Removed UK Responsible Person designation in line with re-registration of the device under a UK-based manufacturer entity.</p> <p>Updated Section 6 to reflect the MHRA Medical Devices (Post-Market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024, including revised serious incident reporting obligations and timelines. Sections 6.1 and 6.4 merged into a single serious incidents and error reporting section. Responsibility for regulatory reporting to the MHRA clarified as sitting with Brainplus UK Limited; users are no longer directed to contact the regulator directly.</p> <p>Minor edits and corrections throughout.</p> | April 2026 |

1. About Ayla – Your CST Assistant

1.1. Product Label

Ayla contains a label that can be found within the application. This label contains the following symbols and information; the symbols are explained here. Some information is specific to the software version and so is not contained here.

| Symbol | Symbol Meaning | Ayla Information |
|---|--|--|
|  | Ayla is compliant with applicable UK product safety legislation. | Ayla is a Class 1 Medical Device compliant with UK Medical Device Regulations 2002. |
|  | Product is a Medical Device. | Ayla is a Medical Device. |
|  | Catalogue Number / Product Code | 001 |
|  | Batch Code / Software Version Number | Software Version Number is shown on the device label. |
|  | Consult Instructions for Use | This document is the Instructions for Use. |
|  | Medical Device Manufacturer / Date of Manufacture | Brainplus UK Limited Innovation Centre, Gallows Hill, Warwick, Warwickshire, CV34 6UW Date of Manufacture is shown on device label. |

1.2. Intended Purpose

1.2.1. Structure and Function of Ayla

Ayla is a software application that supports a range of health and care professionals in planning and delivering Cognitive Stimulation Therapy (CST) — a psychosocial group therapy for alleviating common symptoms associated with dementia such as cognitive decline in people with dementia (PwD).

Ayla contains preconfigured CST sessions for each of the main CST themes consisting of activities that include text, images, sounds and videos and provide guidance and materials for the therapist to configure and personalise sessions according to the age, and cognitive and physical abilities of the PwD participating in the group sessions. This content is developed, adapted and curated based on the CST Manual.

Ayla is able to display materials on a single or multiple displays and provides audio output.

1.2.2. Intended Population and Indication of Ayla

The intended population is identical to that identified in the CST manual and includes:

People with mild to moderate cognitive impairment (as per MMSE test or similar) caused by dementia.

People who do not have severe hearing impairment (even with any aid).

People who do not have severe visual impairment (even with glasses).

Should not have any severe physical health problems that may impact their ability to attend all or most of the in-person sessions.

Able to remain in the session (group) for the duration of the session, approximately 1 hour.

Intended Users of Ayla

Ayla is intended to be used by trained CST practitioners and medical professionals trained in the principles and practice of Cognitive Stimulation Therapy.

1.2.3. Intended Use Environment of Ayla

Planning — General interior room environments, e.g. in-clinics, outpatient settings, care homes, offices.

Delivery — Ayla is intended to be used in a small meeting room-type environment with a group of 5–8 PwD present.

1.2.3.1. Minimum System Requirements

| Criteria | Minimum Requirement |
|------------------|---------------------------------|
| Operating System | iOS v12 OR Android 4.4 (KitKat) |
| Screen Size | >=600 DP smallest width |
| Browsers | Firefox, Chrome, Safari, Edge* |
| Download Speed | >=10 Mbps |
| Memory (RAM) | 1 GB |
| Storage | 8 GB |

*Tested on versions Chrome 124.0.6367.61, Firefox 127.0.2, Safari 17.4.1 (19618.1.15.11.14) and Edge 126.0.2592.87

1.3. Performance Characteristics

Ayla will deliver equivalent benefits as those observed following group CST sessions delivered without the product:

Improved cognitive abilities corresponding to 6 months of cognitive decline following 7 weeks of twice weekly CST.

Improved self-reported Quality of Life.

Increased communication and social interaction.

1.4. Residual Risks

No residual risks to include.

2. Table of Contents

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3. Usage Instructions

You may also find interactive instructions on using the product using the following link:

<https://guidejar.com/guides/6b73e39d-3ba2-4eca-ade0-84f3537c0f38>

3.1. Access to Ayla

To access the Ayla digital interface, simply open a browser on your computer, laptop, or tablet. Ayla works on most modern browsers and is actively tested in Edge, Safari, Chrome and Firefox.

3.2. Log in / Log out

The first time you open Ayla in your browser, you will see a screen where you need to log in. Here you must enter the username and password you have been given from Brainplus UK Limited.

- Avoid sharing your login information with others.
- Ayla will remember that you have logged in for two weeks. Make sure to save your username and password in a safe place in case you get logged out.
- Your saved choice of content and CST groups can be accessed from any device, as long as you use the same username and password to access Ayla.
- You can log out by opening the menu at the top right corner (3 horizontal lines) — click settings — click log out, at the bottom.

3.3. Homepage

The homepage will initially show a drop-down menu to select previously created group, and a plus sign to create a new group.

The sessions can only be accessed through a created group, and the content can then be customised for that specific group.

3.3.1. New group

To create a new group select the plus sign on the homepage. To create a new group you will need to do the following:

- Add a group name.
- Select either sessions from the basis bundle, or copy from a previously created group.
- Filter all sessions by dementia severity (mild, moderate, or mixed), mobility (easy, medium, difficult), and age specific content (born in the 30s & 40s, the 50s, or the 60s).

3.3.2. Session overview

The session overview is designed to provide a quick overview of all the session topics described in the CST manual. When you click on a session in the overview, the selected session will be enlarged and displayed in full screen.

You can choose to start a group session on the overview screen or select the session in advance.

3.4. Session Content

3.4.1. Talking points

Almost all slides in a session have a set of corresponding talking points. The talking points are meant as conversation starters or inspirations. As the group's conversation progresses, you should come up with in-depth or follow-up questions, depending on the group's needs.

You can choose whether to display or save the talking points as needed.

If the talking points are visible, press the "X" to hide them.

If the talking points are hidden, tap on the right side of the large image, near the edge of the screen.

Some talking points can be adapted to better suit the needs of the group. To learn how to edit talking points, please read the "Editing Content" in section 3.5 of this user manual.

3.4.2. Session entry page

The start of a session will show an image related to the topic, with the session theme at the bottom left side of the page. On the bottom right of the screen there is the start button, which if clicked will show a pop-up window asking if you want to prepare or deliver a session, or return to the homepage. Selecting prepare will take you into edit mode — see section 3.5 for more information on editing session content.

In Deliver Mode, the menu navigation available in the top right hand side will show an Edit button next to the session theme. This also gives you the option of preparing for a session, alongside going straight to main activities.

Next to the Start button there is also a printer icon, enabling users to print a pdf summary of Today's session and Next session. These will be configured to show the content pre-generated unless the user has adapted co

3.4.3. Introduction

The session introduction is a single slide. It is designed to provide a brief introduction to the topic of the day, including questions appropriate to the chosen topic of the day. The questions typically relate to the past, participant's childhood or early life.

3.4.4. Reality Orientation Board

The reality orientation board (RO board) makes it possible to do the basic reality orientation exercises inside Ayla. The RO board includes the following exercises:

Group name

The RO board will ask the group to come up with and type in the group name on the board inside the product. This can be completed each session and is intended as an exercise where the group can come up with and try to remember their group name. There is no right and wrong answer, and Ayla does not check what was written in previous sessions.

Date

The RO board asks the group to choose which day of the week, date, and month. It doesn't check if what you type is correct.

Time

The RO board asks the group to provide the time. A clock is displayed, with two fields below to write the hour and minutes. It is up to the group to agree on what time it is and your task

to type it in the fields. The hands will move depending on what you type. It doesn't check if the time you type is correct.

Sing a song

Finally, the RO board asks the group to select a song. You have the choice to use one of your own songbooks, or to choose a song in the YouTube player in Ayla.

Under the YouTube player we have created a range of music playlists showing music from different decades. Once you have selected the list, you can click on the 3 horizontal lines in the upper right corner of the YouTube player to see all the songs that the selected music list contains.

You can also click on the YouTube logo at the bottom right of the player, which will open YouTube in a new tab in your browser. This makes it possible to search for specific songs on YouTube if needed. If you choose to open YouTube in a new tab, you can simply close that tab again when you're done and return to the Ayla tab.

3.4.5. Mental warm-up

The mental warm-up activities are activities aimed at anchoring participants in the present. The warm-ups are not linked to the chosen topic of the day and are generally broader topics of conversation about the present and their reality.

You can replace the mental warm-up activity with an alternative mental warm-up activity if you think it's necessary.

To learn how you can change activities using Prepare Mode, please read section 3.5: "Editing content", in this user manual.

3.4.6. Physical warm-up

The physical warmup is an activity that is meant to get the participants moving. The activity is not linked to the selected topic of the day.

You can replace the physical warm-up activity with an alternative physical warm-up activity if you think it's necessary.

To learn how you can change activities using Prepare Mode, please read section 3.5: "Editing content", in this user manual.

3.4.7. Main Activities

By default, Ayla will generate a choice of three activities related to the session theme. If, when creating a group, you do not add any filters then the default activities will be suitable for both mild and moderate dementia. If filters were selected when creating a group, then the default activities will follow the filters. For example, if moderate dementia is selected then only activities suitable for mixed or moderate groups will be included in the default activities.

Once an activity is selected and completed Ayla will ask if you want to do another activity. If you click "Yes", you will return to the screen where the group can choose another activity. It's up to you to decide whether you have time to do another activity or not. If you don't want to do any more activities, click "continue to finish". This will take you to the last slide of the session.

To learn how you can change which activities are part of the main theme, please read section 3.5: "Editing content" in this user manual.

3.4.8. Closing

The last slide of the session is the ending. It usually includes a brief summary of what the topic of the day was and asks a final question to the group, focusing on the present or the future. Feel free to elaborate on the summary with specific highlights from the session. When you click the next button, you go back to the session overview page.

3.4.9. Session feedback

At the end of a session there will be an opportunity for the group to give feedback on their thoughts about the session. There will be the following three questions:

How much did you enjoy the session?

How engaging were the activities?

How do you feel after today's session? (sad face, neutral face, smiley face for options)

3.5. Editing content

Editing the content of sessions is optional. If you start editing, you will have greater freedom of choice in the content. Adapting the content can potentially motivate the group better but will also require more time preparing.

The editing features give you a quick and easy tool to edit all 14 sessions.

Always make sure you are in the correct group before starting a session to edit.

3.5.1. Preparation

The preparation feature is designed for you to review an entire session, change it as needed, and gather an overview of how the entire session will go.

Once you've created a group, in the "group sessions" section, you're ready to edit a session.

Select the session you'd like to edit.

Select start and prepare in the session entry page.

This will open the session's introduction slide and start the edit mode for that session. While you cannot change the overall structure of the session, talking points and activities can be customised according to the needs of the group.

Once you've pressed prepare and are therefore in edit mode, you can freely click back and forth in all session activities and slides. Every time you make a selection, the selection is automatically saved. Once you have clicked through the entire session and pressed the "next" arrow on the exit slide, you will end up back in the session overview page. All your selections are automatically saved to your selected group and session, and you are no longer in edit mode.

If you would like to continue editing, select a new, or same, session and click prepare again.

For a full list of editable content and how to edit it, please read the "Editable Content" section of this user manual.

3.5.2. Editing with the menu

There is an alternative way to edit a session than selecting prepare at the start of a session.

The Edit function is a tool for when you already know the selected session content and just want to change something specific somewhere in the session, without having to click through the entire session.

Make sure you're in the "Group sessions" section and select the session you'd like to edit. Instead of clicking start, you can click the Ayla menu in the upper right corner of your screen.

It will open the menu and show you an overview with all the chapters of the selected session, as well as a few options.

Click on the section of the session you would like to edit — open the menu again — and click the pen and paper symbol. This will launch the edit mode so you can quickly make the changes you'd like to make in the session. If you want to edit another part of the session, you can simply open the menu and select another section of the session that you want to edit.

Once done with edit mode, click exit on the top right of the screen. This will allow you to switch to deliver mode, or return to the homepage. Clicking delivery will take you back to the introduction slide of the session.

You can always edit the session by pressing edit in the menu or prepare before entering the session.

Remember! The choices you make in edit mode are saved only to the group you selected. The selections will only appear in the group's session that you have been editing.

3.5.3. Editable content

Most content in a session in Ayla can be modified to suit the needs of the group.

All editing can either be done in the sidebar menu, or when on the slide itself in the session.

3.5.3.1. Sidebar editing

In the sidebar menu the session is split into R.O. Board, Warm-up, and Main Theme. Click the drop-down bar on one of these sections to see the activities.

3.5.3.2. Activity selection

For Mental Warm-up, Physical Warm-up, and Main activities you choose from a list of activities. At the top of the list, you can choose to filter by dementia severity (appropriateness) and physical difficulty. You can also choose to only see activities that don't require download material, or activities that don't require additional items.

Mental warm-up: You can only choose one mental warm-up activity at a time in one session.

In the sidebar: Click the drop-down bar for Warm-Up, click on the symbol of two arrows next to Mental Warm-up, select one activity from the selection.

In the activity slide: Click on the pen and paper symbol on the right side of the page, select one activity from the selection.

Physical warm-up: You can only choose one physical warm-up activity at a time in a session.

In the sidebar: Click the drop-down bar for Warm-Up, click on the symbol of two arrows next to Physical Warm-up, select one activity from the selection.

In the activity slide: Click on the pen and paper symbol on the right side of the page, select one activity from the selection.

Main activities: As a starting point, 3 activities are always selected for the main theme of a session.

Your group participants will be presented with a screen of options when they reach the main theme of the session. It gives them a choice in what activities they want to do, which is recommended in the CST manual.

When editing a session, you can decide to select only one activity if you don't think providing a choice is suitable for a particular group.

In the sidebar: Click the drop-down bar for Main Theme, click on the plus symbol at the bottom of the listed activities, select one activity from the selection.

In the activity slide: Go to Today's Activities page, click on the pen and paper symbol on the right side of the question "Which activity should we do today?", select the chosen activities from the selection.

We do not recommend that you choose more than 3 activities.

3.5.3.3. Talking points

Several main activities allow you to select an alternative talking point. Alternative talking points are generally found when a question doesn't work in all situations.

Example: Asking the group about the area they are in when no one knows the area.

Therefore, you sometimes have the opportunity to choose another variant of the same question that fits better.

If the topic may be a sensitive area for the group, there will often be an alternative talking point with a different topic.

Example: When talking about families there is a talking point on religion. This can be changed to a talking point on birth rates.

In the sidebar: Click the drop-down bar for Main Theme, click on the pen and paper symbol for the activity you want to review/edit. If the text can be edited, there will be a sideways pointing arrow next to the header "Talking point group". Click the arrow to see your options. Click save at the bottom of the window to save your changes, or cancel to return to the original content.

In the activity slide: Go to the activity. If text can be edited on a slide, then the pen and paper symbol will be in the text box. Select this to see the talking point options.

3.5.3.4. Images

Several main activities allow you to select an alternative image. Generally if there are multiple talking point options there will be alternative corresponding image options.

Example: Talking points options for religion and for birth rates each come with a different image option.

For alternative images related to talking points, follow the same instructions as for editing talking points above, and click on the pen and paper symbol on the image.

Some activities have different images for different age groups. For example, in the politicians activity in Current Affairs you can choose between Churchill for those born in the 30s and 40s, Harold Wilson for those born in the 50s, or Margaret Thatcher for those born in the 60s.

In the sidebar: Click the drop-down bar for Main Theme, click on the pen and paper symbol for the activity you want to review/edit. If there are different age options for images in one of the slides, the orange bordered box will say "Select time period for images". If there aren't

age options, the box will say "No age specific content". Click on "Select time period for images" box, select preferred age group (by year of birth), select an age-appropriate image from the selection that appears at the bottom of the screen.

In the activity slide: Go to the activity. If the image can be edited on a slide, then the pen and paper symbol will be in the text box. Select this to see the image options. Select your chosen image.

3.5.3.5. Filters and tagging activities summary

When you select to change activities in prepare/edit mode, in the "group sessions" section, all activities are marked with some tags that show which degree of dementia (mild, moderate, mixed) and which mobility severity (easy, medium, difficult) the activity is suitable for.

You can use these tags to filter which activities are presented to you. If you don't select any filters, all activities available will be visible in the list.

Filtering is designed to make it easier for you to filter activities according to your group's overall abilities.

Some activities have additional tags, including whether there is sensitive content, or if additional items should be brought to the session. You cannot filter activities based on these additional tags.

Individual slides within some activities have different images available for different age groups.

Filters added when creating a bundle will affect all the sessions. If you go in to edit a specific session, you will be overwriting the general bundle filter for that group.

Edits made in a session in one group will not affect that session in any other group.

3.6. Feedback

3.6.1. Group feedback

At the end of the sessions there is a reflection section, where you can ask the group about how they found the session and enter their responses.

There are the following 3 questions for the group: How much did you enjoy the session? How engaging were the activities? How do you feel after today's session?

All questions can be responded to by selecting one of 5 stars. 1 star is the most negative option, and 5 stars is the most positive option. For example, if the group felt unhappy or sad at the end of the session, you would select 1 star.

3.6.2. Therapist feedback

Once you have delivered a session there is also the opportunity for you to give feedback.

In the homepage of the group where you delivered a session a small speech bubble symbol will appear underneath the session thumbnail. Click on this to give feedback.

There are the following 4 questions about the session for the therapist: How much did the group enjoy the session? How engaged was the group with the session? How would you rate the overall quality of the session? Did the session provide an appropriate challenge for the group?

You may also leave a comment after answering the questions if you wish to give further feedback.

3.7. Extra material and information

3.7.1. Download material

Some activities contain download material necessary for participating in the activity. For example, a bingo activity would include bingo cards to print out.

If you do not want activities that require downloading material, then in the activity selection menu you can filter by selecting the box next to "Doesn't contain download material".

In the sidebar: Click the "Support material" tab on the right side of the sidebar. Either click "Download all (zip)" to download all possible material for your selected activities, or click the downwards facing arrow next to the activity you want to download material for, then click the download symbol next to the material listed under the activity.

In activity selection menu: Go to the activity selection window needed (for mental warm-up, physical warm-up, or main theme). See section 3.5.3.2 to see how. Click "Download Material" under the chosen activity, if available. The material will then be downloaded to your device.

3.7.2. Suggested items

Some activities require additional items beyond what is provided in the product. For example, the activity Boules requires a boules set to be brought to the session.

Any additional items required are included under "Suggested items".

If you do not want activities that require additional items, then in the activity selection menu you can filter by selecting the box next to "Doesn't require additional items".

In the sidebar: Click the "Support material" tab on the right side of the sidebar. Click on the downwards facing arrow next to an activity. If a selected activity requires additional items, it will be listed here.

In activity selection menu: Go to the activity selection window needed. Click "View suggested items" under the chosen activity, if available. See items listed in a pop-up window.

3.7.3. Summary print out

For each session it is possible to print out a pdf summarising the session. You may either print a summary of the current session or the next session. These can be used for record keeping, and can be given to group participants before or after a session.

Both contain the session name, number, a summary of the discussion topics in general, and a summary of the warm-up activities.

All main activities selected for a session are shown, including the activity title and the thumbnail image.

If you print out the current session summary to share with the group at the end of the session, it is advised that you circle the main activities that were chosen by the group that session.

Click the upwards facing arrow in the bottom right of the start screen for a session. Choose to print a summary of either today's session or the next session. If desired, enter information about the date and time of the session. When printing a summary for the next session, you may also add a phone number to contact if someone cannot attend the session. A PDF of the summary will be sent to the printing setting on your device.

3.8. Suggested group sessions

We've gathered a few suggestions from existing users on how best to incorporate Ayla into your group CST sessions for inspiration. Ultimately, of course, it's up to you to decide how best to do it, based on access to materials, surroundings, and budget.

A large screen for sharing content in Ayla

We recommend showing Ayla on a large screen, presented towards the group in a way that everyone can see the screen equally well.

Speakers

We recommend having a set of speakers to play sounds and music from Ayla and other sources when useful.

Table and chairs

We recommend having a table for tactile experiences and where you can place physical objects. Place the table in front of the screen in such a way that everyone can sit around the table, can all reach what is on the table, and where everyone can see the screen.

Tactile experiences

The digital Ayla platform is not intended to exclude physical activities and tactile experiences. Ayla aims to help start conversations, give structure to the group session, provide a shared focus for the participants, and to make preparation easier for you. Tactile materials are a great way to engage and involve the group and should be included in the session as much as you find useful.

4. Preparatory Instructions

4.1. Operating conditions

This product requires internet access to operate. For videos to run, and for fast reaction time, the internet connection should be stable.

When delivering a session to a group, the device used to display the product should be sufficiently large that all the group can easily see the session content. It is recommended not to display the session on a tablet when delivering to a group.

4.2. Installation Prerequisites

This product does NOT require any third-party apps or plug-ins.

The hardware used for the product should be compatible with the software, as outlined in section 1.2.3.1 Minimum System Requirements.

4.3. Data Privacy Considerations

This product does not collect any personal or sensitive data. Emails for users are stored in the backend of the database.

Data from the product is kept unless requested, or if an account is deleted.

5. Maintenance Instructions

5.1. Software Updates

If you have downloaded the product from the app store, please check regularly for new updates.

Updates may include new content, new features, or bug fixes.

6. Troubleshooting

6.1. Serious Incidents and Error Reporting

If Ayla malfunctions or behaves unexpectedly in a way that has caused, or may have caused, a serious deterioration in the health of a person using the platform, you must contact us immediately using the details in section 6. Do not delay. As a registered medical device, serious incidents are subject to strict regulatory reporting timelines, and we are required to notify the MHRA within days of becoming aware of an incident. Your prompt report to us is essential for us to meet this obligation.

This includes malfunctions or deteriorations relating to the Product Label or these Instructions for Use.

We will manage all regulatory reporting on your behalf. You do not need to contact the regulator directly unless you wish to.

If you have identified an error or bug that has not resulted in any harm or risk to a user, you can report this in either of the following ways:

- include it as feedback in the open text box within the platform
- Contact us directly at support@ayla-care.com.

We review all feedback and error reports and will follow up where appropriate.

6.2. Common issues

If you are not connected to the Internet, a red banner will appear at the top of the page stating, "Be aware that you are not connected to the Internet." Check the Internet or WIFI settings on your device to make sure you have a connection to the Internet.

When using a browser, if an image is missing and replaced with a grey screen, refresh the page to fetch the missing content.

If the content is displayed in an incorrect language, go to the menu in the top right corner of your screen, click settings and change the language in the dropdown menu.

If you have trouble logging in with your password, click "I forgot my password" on the login screen and type in your email. You will then receive an email with a link to create a new password. The email might take a few minutes to arrive. Also, check your spam folder if you suspect you haven't received the email.

6.3. Account Maintenance

If you wish to delete your account, please click the sidebar menu whilst on the homepage.

Select Settings.

"Please delete my account".

If you choose to delete your account, all edited content will be lost.

If you wish for all user data associated with your profile to be erased, please contact support@ayla-care.com

If you need support, for example because you have forgotten your password, or need technical assistance, please contact support@ayla-care.com.

6.5. Support Contacts

Contact support@ayla-care.com if you have any questions or need technical assistance.

6.6. Regulator Contacts

| Country | Contact Details |
|---------|--|
| UK | Medicines and Healthcare Products Regulatory Agency (MHRA) — https://yellowcard.mhra.gov.uk/ |