



iHeadache™

Capture real-time information on your headaches



Feel it.



Record it.



Analyze it.



Send it.

User Manual

Brought to you by:

BetterQOL.com™
Improving quality of life for patients and their physicians

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iHeadache™ Quick Start Guide

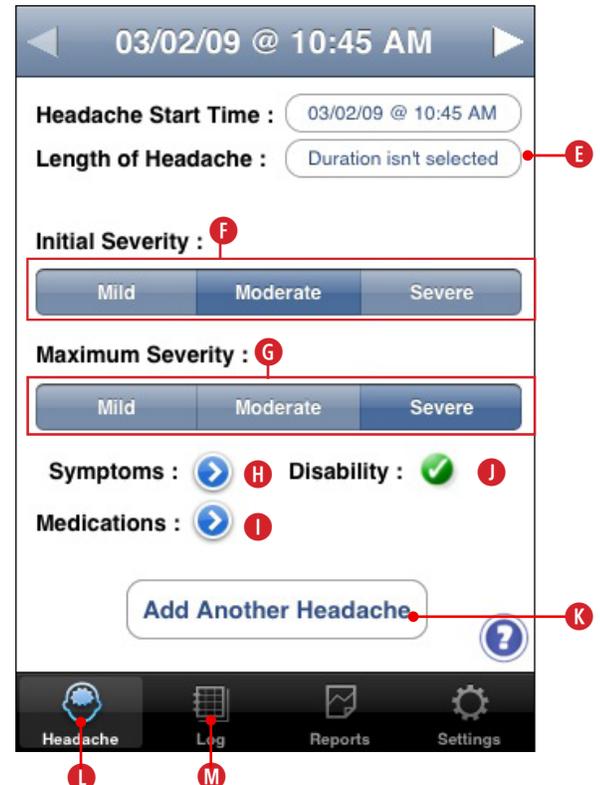
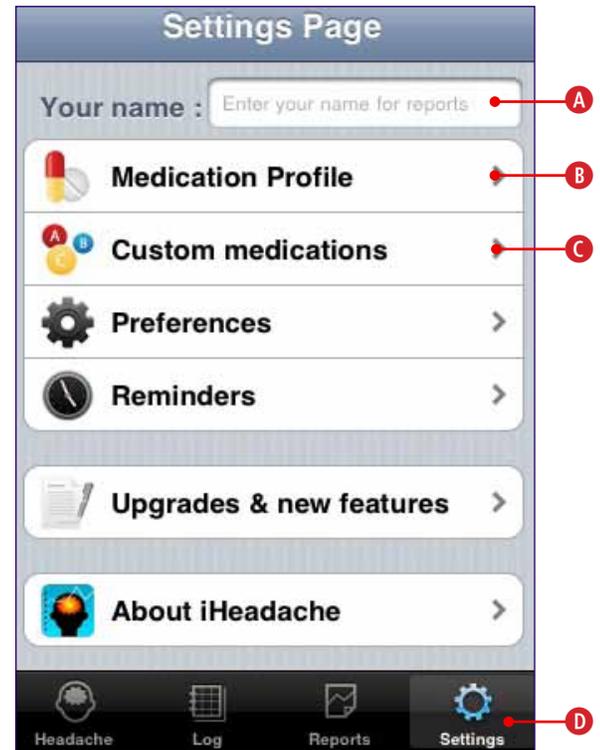


Welcome to iHeadache™! Tracking your headaches including symptoms, medications and disability will help you receive better care. This Quick Start Guide provides an overview of iHeadache's key capabilities.

Getting Started

The first time you start the app the system will automatically start the first headache. Just say ok and do not worry about it now, you can modify the date and time later.

- 1 Set Your Preferences by pressing the **D Settings** button, and fill in your **A name** to use on reports. Go to the **B Medication Profile** and add all the medications that you currently take to treat your headaches. If your medication is not in the system you can add it manually in **C Custom Medications**.
- 2 Enter a headache from either the **M "log"** page (see next page) or the **L "Headache"** page. The system will automatically start a headache the first time you open the App. You can begin entering information about the first headache you are going to log. When you need to begin a new headache you can tap the button **K "Add Another Headache"** on the Headache screen.
- 3 Update **E the headache duration** as your headache progresses. If the headache has been present for a while, you may want to set the duration at this time. You can always update it later if the headache lasts longer.
- 4 Set your **F initial pain** and **G maximum headache pain** to this point of the headache. Come back and update your maximum pain at any time if your headache gets worse.
- 5 Enter your **H symptoms**. All questions must be answered with either "yes" or "no" in order for you to save. You can come back and update the symptoms at any time so if you have any new symptoms as your headache progresses, be sure to come back and enter them.
- 6 Enter **I medications** taken for the headache and the time you took them. It is best to go to medication page and enter the medications when you take them. The medication time is automatically set to the time you enter the medication, however you may edit it.
- 7 Enter your **J disability** caused from the headache. It is generally best to enter your disability information at the end of the headache. Enter the amount of time you felt you were *totally disabled* (unable to function and were generally in bed. Include the time you were sleeping if this is not the time of day you would normally sleep) and the amount of time you are *partially disabled* (still working or playing but not as well).





iHeadache™ Quick Start Guide

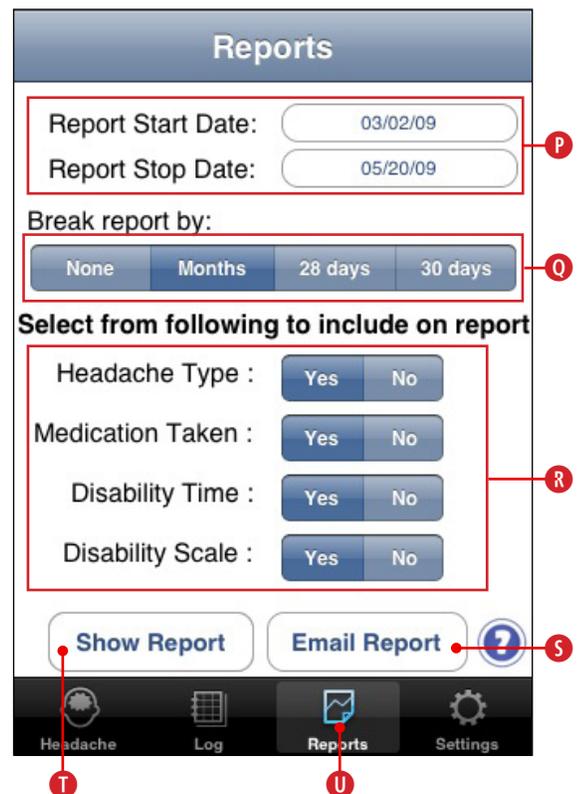
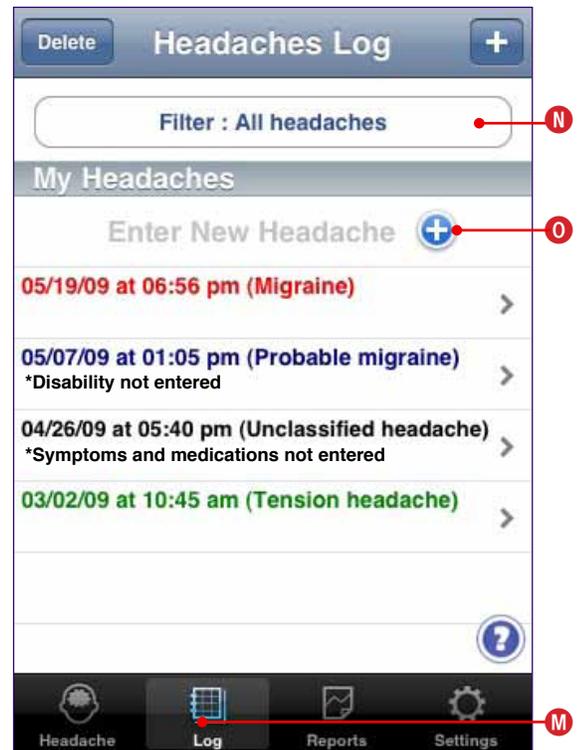


- 8 You can enter new headaches from the **M** “log” page by tapping on the **O** “Enter New Headache” button. The log screen lists all the headaches that have been entered to date. Use the **N** “Headache Filter” to find headaches with missing symptoms, disability, duration and medication.

Generating Reports

The reports are designed with both you and your health care provider in mind and they offer a wealth of information. In general, since headaches come and go, it is best to look at headaches over periods of time.

- 9 To generate a **U** report press the button at the bottom of the screen, then select the **P** start and stop dates for the report. This can include data for up to one prior year. You can break the reports by **O** calendar months, 30 day periods, or 28 day periods (4 weeks).
- 10 Discuss with your healthcare provider what to **R** include on the report. In order to view the report press **T** “Show Report,” and to send it to your doctor, press **S** “Email Report.”
- ◆ Your headache type is determined from your symptoms, duration and medication taken according to International Headache Society criteria.
- ◆ In a study performed by headache experts on patients with disabling tension headaches - real time diaries proved 30% of patients were misdiagnosed. More than of patients with migraines are misdiagnosed with tension and sinus headaches. Some diagnosis require not only knowing how many total headaches you have, but also how many individual headaches meet criteria for migraine. iHeadache™ will do this for you and your doctor. If you have frequent headaches this app will allow your physician to make a more accurate diagnosis.
- ◆ Medication use is summarized and reported by time frame. It shows medications taken for headaches and can show the possibility of rebound headaches - also known as medication overuse headaches.
- ◆ Your disability is calculated by the system. The system reports the time you are disabled and partially disabled from your headaches and calculates your *MIDAS® score. MIDAS® is a disability scale commonly used in migraine studies. A score of 6-10 means you have mild or infrequent disability. A score of 11-20 means you have moderate disability. A score over 21 means you have severe disability.



*(From Stewart WF, Lipton RB, Dowson AJ, et al. Development and testing of the Migraine Disability Assessment [MIDAS] Questionnaire to assess headache related disability. *Neurology* 2001; 56 [Suppl 1]:S20-28, with permission.) Migraine Disability Assessment, (MIDAS®), has graciously allowed for patient use with their doctors.

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Chapter 1: Welcome to iHeadache

1.1 What is iHeadache?

iHeadache, an app for the iPhone and iPod touch, captures real time information about your headaches. Real time information aids the patient and physician in making an accurate diagnosis. Studies have demonstrated that the misdiagnosis of the type of headache results in the patient not being prescribed the most effective medication.

iHeadache is an expert system. It classifies your headache type by analyzing your symptoms, the duration of the headache and medications taken. It follows the International Headache Society Criteria (IHS Criteria) and classifies your headache as a Migraine, Probable Migraine, Tension Headache or Unclassified Headache.

The application tracks the following data:

- *Symptoms* - iHeadache records symptoms common with various types of headaches. The symptoms you enter into iHeadache are what determine the type of headache you are having.
- *Disability* - iHeadache captures the amount of time your headaches result in complete and partial disability. It also captures the degree that you are disabled using the Migraine Disability Assessment Scale (MIDAS scale).
- *Medication Usage* - Overuse of some medications can cause rebound headaches. Capturing medication usage will lead to improved recognition of overuse
- *Number of Headaches* - Some headache types are classified by the number of headaches a patient has over a period of time as well as the individual type of headache the patient is having. iHeadache records the total number of headaches and the various types.

iHeadache was developed by Dr. Brian D. Loftus of Bellaire Neurology. Dr. Loftus is a private practice neurologist. His practice emphasizes headaches, epilepsy, multiple sclerosis and neuropathic pain. He has presented research at various national and international meetings.

1.2 Quick Start Videos

We've put together a series of tutorials of common iHeadache functions; watching them are probably the best way to get acquainted with the software. There is also a quick start guide. Then, if you want to learn more, this manual will still be here when you're done!

Tutorial 1: Setting Preferences

Shows how to setup the medication profile, custom medications, and application preferences.

Tutorial 2: Entering Headaches

Shows how to enter a headache. Also covers entering symptoms, disability, and medication. Navigation, Log Screen, and finding headaches missing data are also explained.

Tutorial 3: Running Reports

Explains how to generate reports and what information is available. Also shows how to view and email the reports.

Chapter 2: iHeadache Settings & Navigation

2.1 The Settings Screen

Before you begin to enter headaches into iHeadache, we recommend that you set a few preferences. Press the “Settings” **5** button on the iHeadache Toolbar to bring up the screen with options for entering your personal settings.

The reports generated from iHeadache can have a name on them. Enter your name **1** and it will appear on your reports. If you prefer not to have a name appear on your reports then enter “none”.



Figure 2A. Settings Screen

2.2 Your Medication Profile

When tracking your headaches it is helpful to record the medication(s) you take to treat your headache. In order to add medications to your headache they must first be setup in your “Medication Profile”. From the “Settings” screen, press “Medication Profile”. **2**

To **add a medication to your “Medication Profile”** (Figure 2B) press the **+** on the line that says “Add Medication”. **7** You will be taken to the “Medication List” (Figure 2C). The most common prescription and over the counter medications for acute headaches are available in iHeadache. Enter the name of your medication (generic or brand name) in the search field **9** to try to find your medication or scroll down the list. If your medication has more than one dose, try to find the correct one. Press the **+** on the medication **10** that you want to add or press anywhere on the name of the medication to see the “Medication Details” (Figure 2C). The Medication Details screen shows the form (tablet, injection, capsule, etc), dose, and other information. Confirm it is the medication that you want and press “Add medication to profile”. **11** If it is not the medication that you want to add press “Back” **8** to go back to the “Medication List”. If your medication is not listed in the “Medication List”, you can add a custom medication by pressing “New Medication” **8**. (See Section 2.3 for setting up custom medications.)

To **delete medications from your Medication Profile** press “edit” **E** on the Medication Profile Screen (Figure 2B) and select the medications you want to delete.

2.2 Creating Your Medication Profile (Con't)



Figure 2B. Medication Profile



Figure 2C. Medication List



Figure 2D. Medication Detail

2.3 Creating Custom Medications

If your medication is not listed by default in the Medication List, you can add a custom medication to your Medication Profile. From the “Settings” screen (Figure 2A) press “Custom Medications” ³.

Enter the name of the medication, the form (i.e. capsule, tablet, injection, nasal spray, etc.) and the dose ¹².

If the medication is specifically prescribed to treat migraines and does not treat any other condition then press “yes” otherwise press “no”. ¹³ (The reason this is important is that some headache diagnosis’s are dependent upon duration of the headache and whether a “migraine specific” medication is taken to treat the headache.)

Press “save” ⁵ when you are finished entering your custom medication or press “cancel” ⁴ to return without saving.

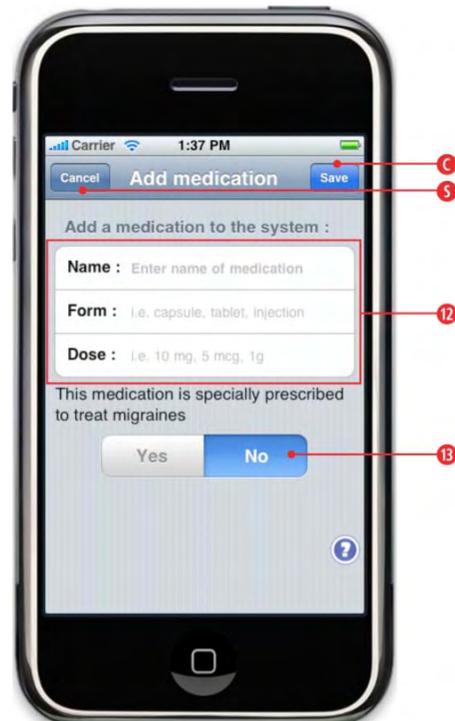


Figure 2E. Custom Medication

2.4 *iHeadache Preferences*

**Please note: Your physician may specify these advanced preferences.*

To edit the following settings press “Preferences”  from the “Settings” screen (Figure 2A).

2.4.1 Headache Order Test Preference

It is possible for a headache to meet the criteria for both “probable migraine” and “tension headache”. Headache experts disagree how these headaches should be considered. According to the most recent definitions of headache from the International Headache Society, the directive is to count these headaches as tension headaches but some physicians prefer to count them as probable migraines. Set the preference by choosing to test for “tension headaches” first or “probable migraines” first. 



Figure 2F. Preferences Screen

2.4.2 Medication Name in Reports

Chose whether to show generic medication names, trade medication names or both on reports. 

2.4.3 Headache Duration Rules

The official diagnosis of an individual migraine headache is one that either lasts at least four hours or goes away when a medication used specifically to treat migraines is taken. For the purpose of tracking or counting migraines, you can chose to do the following with the length of the headache: 

- **Ignore the Duration** – Whether the duration is entered or left blank, the duration will be ignored and only the symptoms will be analyzed to determine the type of headache.
- **Use the Duration if Entered** – If the duration is entered then it will be used along with symptoms to determine the headache type. If duration is left blank then only the symptoms will be analyzed to determine headache type. This will be the default setting until it is changed.
- **Require Duration** - The duration of the headache is required in order to determine the type of headache.

2.5 *Basic Navigation in iHeadache*

The basic navigation is outlined below so that you can efficiently enter information into iHeadache. iHeadache is designed for you to enter information about your headache as it

progresses. For example if you start entering your symptoms at the onset of your headache and additional symptoms develop, you can go back and update iHeadache with your new symptoms.

2.5.1 The iHeadache Toolbar

The iHeadache toolbar appears at the bottom of all screens. ¹⁷ Any time you need switch between functions the program will remember your previous entries so you will not loose the data you have entered.

Example: You are entering a headache but decide you want to look at the “Log” to see how many headaches you have had recently. You can look at the “Log”, then return to “Headache”, and finish entering your headache without loosing any data.

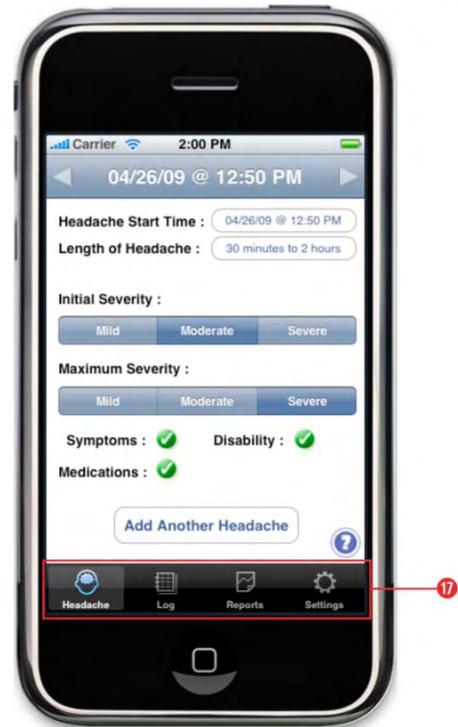


Figure 2G. Example of the iHeadache Toolbar

The following appear on the iHeadache Toolbar:



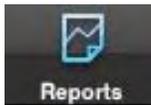
Headache

Enter headaches including start date, duration, severity, symptoms, disability, and medication taken.



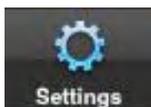
Log

View a list of all your headaches sorted in chronological order. You can also find headaches that are missing medication, duration, symptoms, and disability information.



Reports

View and email reports about your headaches. Select various criteria, time periods, and report dates.



Settings

Set up your personal medication list, add custom medications and specify preferences.

2.5.2 Using the Headache Log Screen

To access the “Log Screen” press the Log ²³ button in the iHeadache toolbar.

The Log screen (Figure 2H) lists all the headaches that you have entered. **Headaches are color coded by type.**

- **Migraines** are **Red**
- **Probable Migraines** are **Blue**
- **Tension Headaches** are **Green**
- **Unclassified Headaches** are **Black**

To **edit a headache**, select the headache you want to edit and you will be taken to the Headache Entry screen. ²²

To **delete an existing headache**, press the delete button ¹⁸ and the delete buttons will appear.

To **start a new headache**, press either the “+” ¹⁹ button in the upper right corner or the ²¹ after “Enter New Headache”. ²¹ (Also see Section 3.4)

The log screen displays a note under headaches that are missing duration, medication, symptoms and disability information. You do not have to enter this information however your reports are much more useful if you do.

The “Headache Filter” ²⁰ can be used to display only the headaches missing certain criteria. Use the headache filter (Figure 2I) to show:

- All Headaches
- Headaches Missing Medications
- Headaches Missing Symptoms
- Headaches Missing Disability
- Headaches Missing Duration

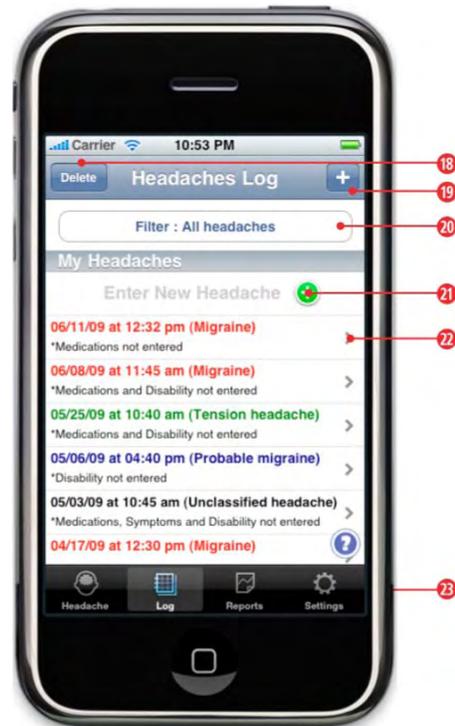


Figure 2H. Log Screen



Figure 2I. Headache Filter

2.5.3 Next and Previous Arrows

At the top of the Headache screen (Figure 2J and Figure 3C) there is a left and right arrow. Use these arrows ²⁴ to **scroll to the next and previous headache**. The date in between the arrows is the headache date. You can edit the headaches as you scroll through them or just view the data.



Figure 2J. Scroll Arrows on Headache Entry Screen

Chapter 3: Entering Your Headache Information

3.1 Your First Headache

The very first time you start iHeadache, a headache entry is created for you. An alert box ²⁶ will appear to inform you of this. Just press “OK”.

This start time of the default headache will be the current date and time. When you are ready to enter your first headache just click the “Headache Start Time” ²⁵ and pick whatever date and time you need.



Figure 3A. Startup Headache Created

3.2 Begin a New Headache

Press the “Headache” button on the iHeadache toolbar. ²⁷

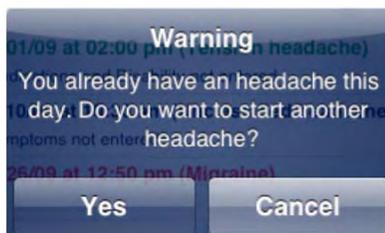
You can begin a new headache at any time from the headache entry screen by pressing the “Start New Headache” button. (See Section 2.5.2 for starting a new headache from the log screen)

An alert box ²⁸ will notify you that a new headache was successfully created. Press “OK and begin entering data about your headache.

If you already have a headache entered on the same day, iHeadache will alert you and make sure you want to start a new headache.



Figure 3B. Confirmation of new headache



3.3 Entering a Headache

3.3.1 Headache Start Time

All headaches must have a start time. ²⁹ When a new headache is created, the start time automatically defaults to the current date and time. The start time can be changed by selecting the start time drop down menu and then selecting the date and time on the picker.

3.3.2 Length of Your Headache

The headache duration field, “Length of Headache”, ³⁰ is optional but may be used to classify the type of headache you are having. To ensure complete reports and an accurate diagnosis it is advisable to enter the duration of your headache. The duration can be:

- Less than 30 minutes
- 30 minutes to 2 hours
- 2 to 4 hours
- Over 4 hours

3.3.3 Initial and Maximum Severity

Select the initial severity and the maximum severity. ³¹ The maximum severity cannot be lower than the initial severity.

3.3.4 Symptoms, Medications & Disability

Information about symptoms ³², medications ³³ and disability ³⁴ is optional but it helps to create a complete headache report for you and your physician. Add or edit these items for a headache by pressing the  next to the section. Once a section has been entered and saved, a  will be displayed.

- For instructions on **entering symptoms** see Section 3.4
- For instructions on **entering disability** see Section 3.5
- For instructions on **adding medication to your headache** see Section 3.6

**Remember: iHeadache is designed for you to enter information about your headache as it progresses. You can initially set the “Length of Headache” and “Maximum Severity” of your headache and always come back in and change them as needed. You can also update your symptoms, medications and disability at anytime.*

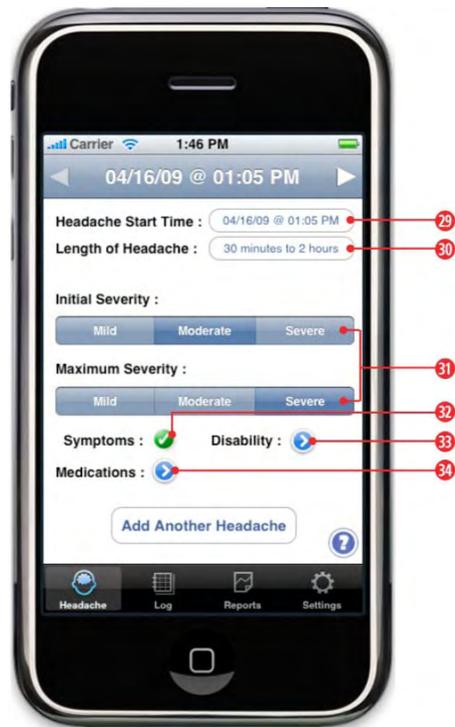


Figure 3C. Headache Entry

3.4 Entering Your Symptoms

*See Section 3.3 and Figure 3C for Headache Entry.

Press  from the Headache entry screen to open the “Symptoms”  screen. Enter your symptoms by answering yes or no  to the questions. You must answer yes or no to all of the questions before you can save. Return to the symptoms page to as your headache progresses if you need to change your answers and update the symptoms. Press “Save”  when you are done or press “cancel”  to return to headache entry without saving.

- An “*aura*” is something that occurs before the headache begins. If you are unsure if you have an aura, answer no for now and ask your doctor about this.
- “*Worse with movement*” means your headache pain is worse with regular movements such as walking around.
- The term “*throbbing pain*” can also be thought of as a pulsating pain or a pain that goes up and down like your heart beat.
- “*Sensitivity to light*” means the headache is more uncomfortable when you are exposed to light or you may feel better being in a dark room.
- “*Sensitivity to noise*” means the headache is more uncomfortable when you are exposed to noise or you may feel better when it is quiet.

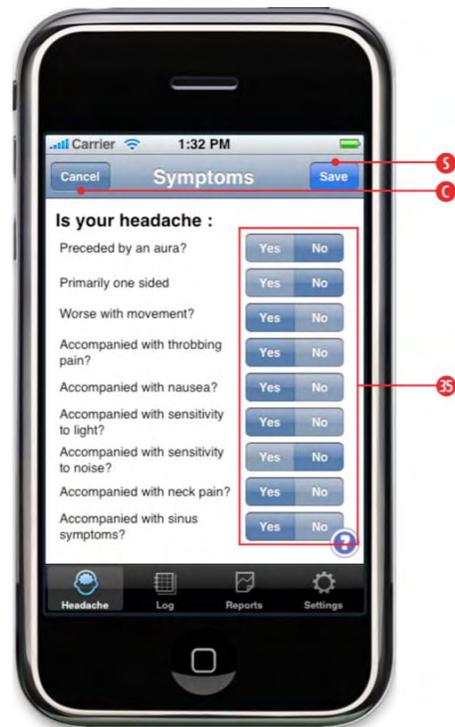


Figure 3D. Symptoms

3.5 Disability from Headaches

*See Section 3.3 and Figure 3C for Headache Entry.

Press  from the Headache entry screen to open the “Disability”  screen. iHeadache uses the MIDAS™ scale . It was originally developed by Robert Lipton. It is widely used in research studies to determine the effectiveness of treatments and their impact on the patient’s disability.

In addition to the MIDAS scale, estimate the amount of time you were “completely disabled”  because of this headache. Also estimate the amount of time that you were “partially disabled” . Do not include time you were “partially disabled” in the time that you were “completely disabled”.

Return to the disability screen as your headache progresses to update information. Press “Save”  when you are done or press “cancel”  to return to headache entry without saving.

**Note: If you answer “Yes” to question 1, question 2 will be disabled. If you answer “Yes” to question 3, question 4 will be disabled.*

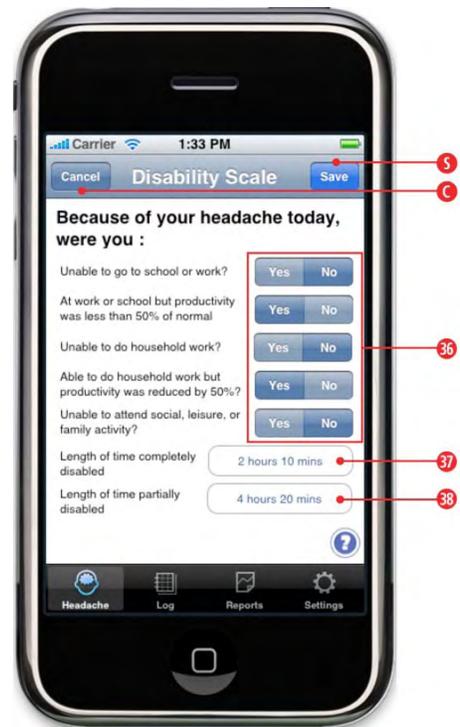


Figure 3E. Disability

3.6 Adding Medications to Your Headache

*See Section 3.3 and Figure 3C for Headache Entry.

Press  from the Headache  entry screen to open the “Headache Meds” screen. You can add medication(s) that you take for your headache here. To enter medication(s) you take, press the  to the right of “Add Medication to Headache” . (Figure 3F)

Select a medication  from your personal “Medication List” (Figure 3G) and enter the time  that you took the medication. Press “Save”  to add the medication to your “Headache Meds” list. Press “Cancel”  to return to the “Headache Meds” screen without adding a medication.

If you are done adding medications to your headache press “Save”  on the “Headache Meds” screen (Figure 3F). To delete a medication from your headache press “Edit”  and select the medications you want to delete.

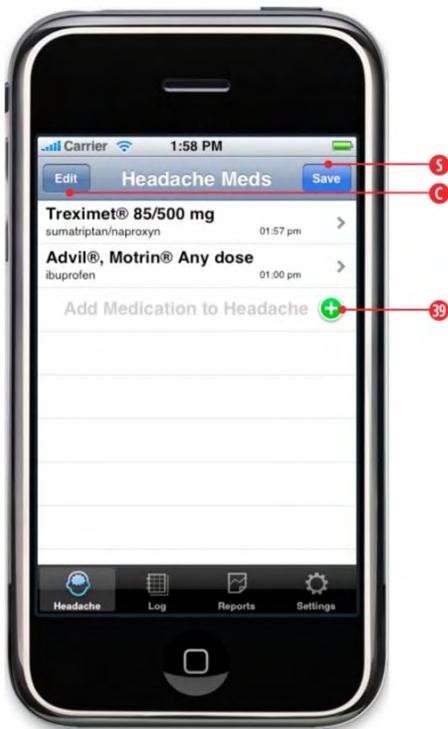


Figure 3F. Medication(s) taken for your headache



Figure 3G. Adding medication(s) and specifying time

3.7 Viewing and Editing Your Headaches

See “Using the Headache Log Screen” (Section 2.5.2)

3.8 Finding Headaches Missing Data

See “Using the Headache Log Screen” (Section 2.5.2)

3.9 Application Help

Help is available throughout the application by pressing the  in the lower right corner of your screen.

Chapter 4: Reports

4.1 Report Options

You can obtain reports on your headaches for up to one year. Pick your start and stop dates ⁴² for the report then choose to view data sorted by ⁴³ the following:

- calendar months
- 30 day time frames
- 28 day time frames
- (none) one complete period of time

Select the criteria ⁴⁴ to include on the report including

- Headache Type
- Medications Taken
- Time Disabled
- MIDAS Disability Scale

You must have at least 30 days of data in order for iHeadache to *estimate* a MIDAS score. If 90 days of data are available the MIDAS score is more accurate.



4.2 Viewing and Sending Reports

To have the most detailed reports possible, all headaches need to have the duration, disability, medication and symptom information filled out. To view your report on your iPhone press “Show Report” ⁴⁵ or you can email it to yourself or others by pressing “Email Report” ⁴⁶.

4.3 Using iHeadache to Optimize Your Headache Care

THE iHEADACHE APP CANNOT DIAGNOSE YOUR HEADACHES. ONLY A PHYSICIAN CAN MAKE A HEADACHE DIAGNOSIS AFTER EXAMINING YOU AND RULING OUT CAUSES OF YOUR HEADACHES. THE ADVICE BELOW ASSUMES THAT YOUR PHYSICIAN HAS DIAGNOSED YOU WITH A PRIMARY HEADACHE TYPE SUCH AS MIGRAINE, TENSION, CLUSTER, ETC.

While there are no hard and fast rules, Dr. Brian Loftus, Chief Medical Officer at BetterQOL, Inc. offers the following recommendations for patients to maximize the benefit of iHeadache in their headache care. It is most important to try and enter all of your headache information at the time the headache is occurring. At the end of the headache or the end of each day, review the headache entry and make sure the information is complete. This is particularly important for your disability time and partial disability time.

While iHeadache cannot make a headache diagnosis and all patients need their headaches

evaluated and diagnosed by a physician at least once, iHeadache can provide useful information concerning the potential accuracy of your diagnosis. The system analyzes headaches to see if the symptoms are compatible with migraine, tension, or probable migraine headache. Cluster headaches are currently not included (although iHeadache can still be used for headache counts and disability) as there is no benefit for tracking symptoms of cluster patients.

Look at your headache reports for the last three (3) months or so.

- How many days per month do you have headaches?
- How many days do you have migraines and how many days do you have probable migraines?

Use the chart below to learn more about specific types of primary headache disease.

| | |
|--------------------------------|--|
| Chronic Migraine | Chronic migraine patients have headaches 15 days per month with at least 8 days of the headaches being actual migraines (averaged over 3 months). |
| Episodic Migraine | Episodic migraine patients commonly have headaches that are tension headaches and probable migraine headaches. For treatment, they can all be considered part of the migraine headache disease process. |
| Tension Headaches | If you have been diagnosed with tension headaches, then none of your headaches should be migraine or probable migraine. If they are, then review options with your physician for taking therapy specifically for migraines. |
| New Daily Persistent Headaches | Every day you have a headache and they are all tension type headaches. The headaches began on a single day and continued daily from the very first day. |
| Infrequent Tension Headaches | Tension headaches occurring less than once monthly on average (over one year). |
| Frequent Tension Headaches | Tension headaches occurring between one and 14 days per month (averaged over 3 months) |
| Chronic Tension headache | Tension headaches that occur more than 15 days per month (averaged over 3 months). |

In one study where headache experts first diagnosed patients with frequent disabling tension headaches, 30% of them proved to have migraine with real time diaries.

Medications for treating migraines are given to patients who get disabling headaches of any type as long as some of their types of headaches are migraines. If you are not on migraine specific medications and your reports indicate significant disability from your headaches each month, then please ask your physician for this medication.

Do you need headache preventatives?

Use reports from iHeadache to determine if headache preventatives are needed. If you are

having significant disability despite you and your physicians best efforts to treat your headaches or if your headaches are more frequent than once weekly, then one needs to consider prevention. Choosing appropriate prevention depends both on the headache type as well as your individual treatment preferences. You and your physician should take into account the following factors:

- Efficacy data for your headache type
- Side effects of the medication
- Cost
- Comorbid diseases (other diseases you have besides headache)
- Personal preference (types of medications you may wish to avoid).

If you are already on a preventative or after starting a preventative, you and your physician need to determine if it is working. Use iHeadache to break reports by months, 30 days periods, etc.. Look at a period of time after the new medication is started compared to the time period before the preventative is started.

- Are you having fewer headache days?
- Are you having less disability compared to before you started the preventative?

If you answer no to both of these questions, then either the dose of the preventative is inadequate or the preventative needs to be changed. Typically, a good response to a preventative is a 30% reduction in the number of days you have a headache and 50% reduction in disability. A great response is more than 50% reduction in the headache days and more than 75% reduction in disability.

iHeadache™ License Agreement

Only a physician can diagnose your headaches. Once serious causes of headaches have all been eliminated, you can use iHeadache™ to keep track of the:

- number of headaches you have.
- severity of your headaches.
- disability caused by your headaches.
- treatment of your headaches.
- type of headache. (migraine, probable migraine, or tension type).

This application determines the type of headache by analyzing symptoms during the headache, duration of the headache and response to migraine specific medication. Most headaches that patients consider to be sinus headaches, stress headaches, and menstrual headaches fall into the above groups.

At this time, cluster headaches are not supported for headache typing by iHeadache™ but patients can use this application to keep track of cluster headache counts and medication usage.

The application will report data by time intervals (months, 30 days, or 28 days). This enables you and/or your physician to use the data to determine if the treatments for prevention of your headaches are working. In addition, the application will report on your degree of disability using a MIDAS® scale and by tracking the length of time disabled. It also tracks medication usage.