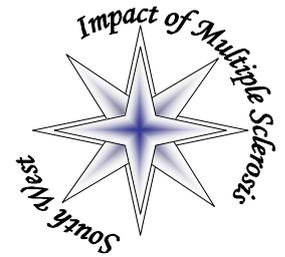


SWIMS News

The South West Impact of MS Project: a long-term study of the impact of MS and CIS on those living with these conditions in Devon and Cornwall



A big thank you to all SWIMS participants

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Welcome to all of the new recruits to the SWIMS Project. We are delighted that you have decided to take part.

And a big thank you to those who have been with us for some time.

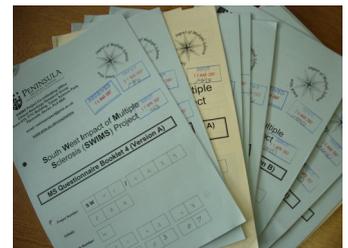
Over 5,000 questionnaire booklets have been received since we commenced the project in 2004. This means that we are well on our way to building a fantastic resource which we will use

to meet the objectives of the project. This resource grows ever more useful to us when a large number of people with clinically isolated syndrome or multiple sclerosis continue to take part over many years. We've made a great start – thanks to all of you – and we hope that you'll stick with the project for the long term.

We know that some questions in the questionnaire booklet may be difficult to answer, or may not be particularly

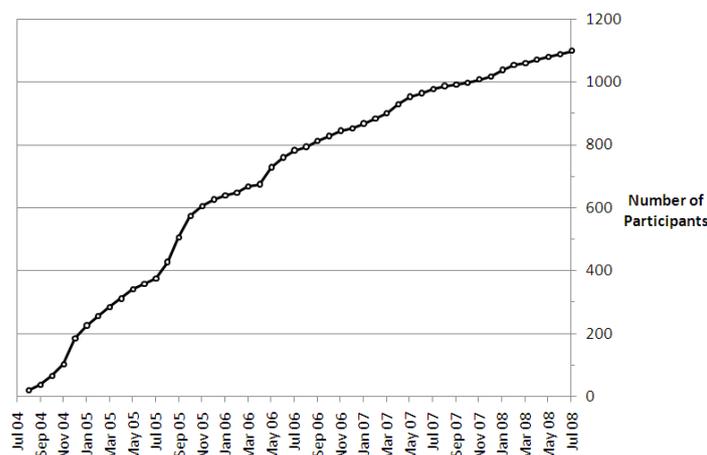
relevant to you. In these situations we suggest that you give the answer that matches most closely to your particular situation wherever possible. Please do not hesitate to contact us if you have a query about your questionnaire booklet.

The SWIMS Project Team



Recruitment Progress

By the end of July 2008, 1,098 of the estimated 2,000 people with CIS or MS in the region had consented to take part in SWIMS (see graph below). We aim to offer as many people as possible the opportunity to take part, so if you do know of anyone who might not have heard about SWIMS then please do spread the word! Penny, our Assistant Coordinator, would be delighted to send further information to anyone who is interested in participating.



New SWIMS researcher on board

“The SWIMS Project will do three things. It will enable us to (1) understand what it is like to have MS or CIS, (2) improve the way that changes in MS symptoms and disability are measured—a vital step forward for the testing of new and emerging treatments for MS, and (3) predict what will happen to individuals with MS over time” **John Zajicek, Chief Investigator for SWIMS.**

Dr Anita Slade has joined the Clinical Neurology Research Group (CNRG) this autumn to work alongside Dr Jeremy Hobart. Anita is an experienced researcher who joins us from Leeds Metropolitan University to analyse the answers you have given for the rating scales in Part 2 of your SWIMS questionnaire booklets. The aim is to

determine which rating scales are good at measuring changes in MS, which are lacking and why, and how such rating scales might be improved upon. This is important work because, when testing new drug treatments and other therapies for MS, it is vital to have a rating scale which measures the condition accurately and in a way that

is meaningful to people with MS and the medical profession alike. With this in mind our objective is to develop rating scales which are relevant and applicable to all people with MS, informative to clinicians, and straightforward to complete.

Dr Hobart is Consultant Neurologist at Torbay Hospital, and a lead researcher at the CNRG.

Are you taking part in the CUPID Trial?



A reminder to those people who are currently participating in the SWIMS **and** CUPID studies that you can opt for a **shorter** SWIMS questionnaire booklet whilst you remain in the CUPID trial. This is because there are four individual questionnaires (rating scales) that appear in your SWIMS **and** CUPID questionnaire booklets. We appreciate how long it can take to complete the booklets and we are keen to

reduce the duplication that sometimes occurs when people take part in more than one study being run by the Clinical Neurology Research Group at the same time. So we have obtained permission from the Research Ethics Committee to give people taking part in both SWIMS **and** CUPID the option to receive a shorter SWIMS booklet. The shorter booklet does not contain the four questionnaires common to both studies. Provided

we have your agreement, the answers given in your CUPID booklet for these four questionnaires are transferred to the SWIMS team, so that the SWIMS database is complete. Absolutely no other information given in the CUPID questionnaire booklet is shared. If you would like more information about this then please do not hesitate to contact us on **0800 015 3430** or email **swimsproject@pms.ac.uk**.

Newsflash...Cannabinoid Use in Progressive Inflammatory brain Disease (CUPID) study...Newsflash

CUPID is a clinical trial that is being run by CNRG to evaluate whether THC (one of many chemical compounds found in the cannabis plant) might slow the development of disability in progressive MS. During the summer the target number of participants required for this trial, i.e. 493, was reached. The team cannot now recruit any further people to this trial. Data collection will continue until 2011, with results expected during 2012. For more information on the CUPID trial, please visit our website: www.pms.ac.uk/cnrg/cupid

Powerful new treatments for RRMS

John Zajicek, Chief Investigator for SWIMS



The characteristic "Y" shape of antibodies.

Adapted from the Medicines Research Council website (www.mrc-lmb.cam.ac.uk)

The good news for people with early MS (who aren't in the progressive phase and are still having relapses that cause real problems), is that there are around a hundred new treatments being tested across the world. In Devon and Cornwall we're taking part in a few of these clinical trials. Many of these treatments are in a class of medicines known as "**humanised monoclonal antibodies**", so I thought that people might like to know a bit about this group of drugs

What are antibodies? Antibodies are a natural part of our immune system, and are present in everyone. Antibodies are produced in response to exposure of "foreign" material in our bodies, such as viruses or bacteria. They usually stick to the surface of invading bugs, which then allows our body to destroy the bugs, and we get better from the infection. We have thousands of different antibodies circulating in our bodies all the time (because of exposure to previous infections), and each antibody recognises different parts of the foreign invaders - this is known as immunity

Antibodies and MS There is evidence that certain parts of the immune system are overactive in people with MS. Based on this, antibodies that "block" parts of the immune process are being developed as treatments for MS. We should therefore be able to "calm down" the underlying MS process.

Humanised monoclonal antibodies Antibodies can be made artificially, usually from animal cells. Large quantities of the same type of antibody (so-called "monoclonal" antibodies) can be made. Many of these laboratory-made antibodies can be adjusted to look like human antibodies (i.e. humanised) in order that they can be given to people as medicine without too much worry about an allergic

reaction. All of these drugs need to be given by injection, as they are destroyed in the person's digestive system.



Tysabri The first medicine of this type to be licensed in the UK is a drug called Tysabri (or *natalizumab* to give it its proper name). This antibody stops the white blood cells that cause inflammation of the nerves from getting in to the brain. In clinical trials this drug reduced the number of MS relapses by over a half, and seems to be much better than other available drugs such as beta-interferon. It is given by injection once a month. However, the downside is that it has been associated with a nasty infection of the brain called PML, which is a rare viral infection with no cure. Unfortunately during the trials two people got the PML infection; one person died and one person survived but was left very disabled. More recently there were two further cases of PML associated with Tysabri use. The other issue with the drug is that it is expensive, and if you include the costs of monitoring and keeping a close eye out for PML, the cost per person is around £15-20,000. Despite this, NICE (the national organisation responsible for providing guidance on treating ill health) have said we are allowed to use Tysabri for aggressive MS, where the risks of the MS are worse than the risks of the drug.



Campath 1H (*alemtuzumab*) Another antibody which we've been using a lot of in clinical trials in Plymouth is Campath 1H. Campath 1H kills a type of white blood cell that causes inflammation of the nerves in MS. This drug is given by drip every day for five days, and then a second course is given for three days a year later. Initial results using this drug in people with bad relapses have shown that it seems to slow down relapses by around 80-90%

Powerful new treatments for RRMS



See page 5 for information about taking part in clinical trials of monoclonal antibodies.

compared to beta interferon – this is a very powerful effect. Again, there is a down side – people that have had Campath can get other problems with their immune system, particularly problems with their thyroid gland and blood clotting. This means that regular blood tests are needed after having had this drug, but once spotted these problems can be treated relatively easily. If given early enough, to people with a certain type of MS, then Campath seems to be the most powerful drug for MS yet developed.

We are now in the situation where an increasing number of these drugs are becoming available – powerful drugs with powerful potential side effects.

There are many unanswered questions such as: if we treat early enough can we stop MS completely in some people? Also,

how can we spot the people whose MS is going to be bad enough to justify the risk of using these powerful drugs?

This last question is something that we're trying to understand from the information you provide for the SWIMS Project. If we can use information early in the disease to predict people who might do badly over the longer term, we might be able to provide better information about the risks and benefits of these drugs. I have no doubt that in future we'll be tailoring medicine to slow or stop MS to every individual with the condition. But we'll only be able to do this properly if we can understand how MS affects people over time – which is what you're helping with by taking part in SWIMS.

Keep SWIMming!!



SWIMS on DVD



You may recall that currently we provide eligible people who might be interested in taking part in SWIMS with an information sheet about the Project. We are now putting together a dvd (or cd) to give to people in addition to the information sheet.

The dvd will highlight the aims of the research conducted at the CNRG, outline what is involved in taking part in SWIMS, and

show the significance of the research into MS. We will introduce the SWIMS Team so that participants will know who is at the other end of the freephone number, should there be a need to contact us.

We are looking for volunteers to feature in the dvd. **Can you help?!** Our colleagues from the Peninsula Medical School's Multimedia Department are doing the filming and editing. The filming will take place at **Mount Gould**

Hospital, Plymouth, on a Monday afternoon, and will involve a short discussion between Prof John Zajicek and a number of people about having MS. We will not include footage unless we have consent from the people being filmed.

If you would like to star in this production, or even just contribute a few words or a couple of seconds of filming, then please do get in touch with us at the SWIMS Project Coordinating Office. *Thank you.*

MS research at the Clinical Neurology Research Group

Are you interested in taking part in a clinical trial?

We are looking for people with **relapsing-remitting MS** to take part in the clinical trials being run by the Clinical Neurology Research Group, details of which are given here. If you might like to take part in one of these studies then please contact Miss Suzi Reilly (Senior Research Nurse) on **01752 315248**, or Dr Nick Pilkington (Research Nurse) on **01752 315261**.

CAREMS I and **CAREMS II** are studies led by Genzyme pharmaceutical company. These studies are both looking at **Campath (alemtuzumab)**, a monoclonal antibody and **Rebif** (Beta interferon) in the treatment of RRMS. CAREMS I is suitable for people who have never previously taken any disease-modifying therapies, whereas CAREMS II is suitable for people who have been on disease-modifying therapy and who have experienced a relapse whilst on the therapy.

What is involved? All participants will receive an active treatment – either Campath or Rebif. Campath is given twice, the first dose is given over five days and the second dose is given one year later over three days as a hospital inpatient. Rebif is given three times a week for the duration of the study by self injection with a small needle under the skin at home.

Study visits to Plymouth are at monthly intervals over two years (and possibly up to four years for CAREMS I). There are regular brain scans (MRI scans).

Participant requirements (not a complete list):

- Age 18 – 50 (CAREMS I), or 18-55 (CAREMS II),
- Onset of symptoms within last five years (I), or ten years (II)
- At least two relapses in the previous two year period with one relapse occurring within the last twelve months.

The **SELECT** Study is a study led by Biogen Idec pharmaceutical company. This is a study to see whether a drug called **Daclizumab** (a monoclonal antibody) can reduce the number of relapses people may have and/or slow the time to any further relapses.

What is involved? Participants will receive either Daclizumab or a placebo (no active drug). Participants will not know whether they have been given active or placebo medication during the study. The treatment period is twelve months, during which time participants receive three injections under the skin once every month. There is then a follow-up period (without treatment) for a further six months. So study visits to Plymouth would be for a total period of eighteen months and must be adhered to where possible. There are regular brain scans (MRI scans).

Participation requirements (not complete list):

- Age 18 – 55 at time of entry to study,
- Had a relapse and a MRI brain scan in the last year, or a very recent MRI brain scan which showed inflammation,
- Can walk 200m without a walking aid,
- Not had steroids, Beta interferon or Copaxone recently,
- No previous treatment with a monoclonal antibody.



CNRG is located at Tamar Science Park, Plymouth

Are you interested in taking part in a genetics study?

“The genetics of complex disease is entering a new and exciting era. The impact of these new discoveries in neuroscience is incalculable at this stage but potentially revolutionary” **Dr Stephen Sawcer, Senior Research Associate, Cambridge MS Genetics Group** (quoted in *Brain journal*, May 2008)

CNRG are pleased to announce a new collaboration with a renowned research group – the **Cambridge MS Genetics Group**. The Cambridge MS Genetics Group have been conducting research in this field for over a decade. The aim of their **Genetic Analysis of MS (GAMS)** study is to identify genes or genetic factors that are important in MS. Genetic factors may influence the likelihood that an individual develops the condition, or the course MS takes over time, or how an individual responds to treatment. Identifying these genes might result in the development of effective treatments and preventative measures.

CNRG are organising the GAMS study locally, which is now open for people with MS who live in the catchment area for Derriford Hospital, Plymouth. We plan to expand the study to

include Torbay and the whole of Cornwall in the near future. GAMS will also be running at the Royal Devon and Exeter Hospital in due course. The MS Society has provided funding for us to conduct this study.

What is involved? A single blood sample is taken from each participant, the DNA is extracted and sent to the MS Genetics Group in Cambridge as an anonymous sample for analysis. Each participant will also be asked to complete a short questionnaire.

Participation requirements:

- Confirmed diagnosis of MS
- Aged 16 years or older

If you would like to know more about this study then please not hesitate to contact Alison Page, the GAMS Research Nurse based at the CNRG, on **01752 315249** or email alison.page@pms.ac.uk.



Alison Page, Research Nurse for GAMS

The SWIMS Project is funded through the Peninsula Medical School Foundation — a charitable body established in 2002 to support research and education—and the Multiple Sclerosis Society of Great Britain.

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