

18 November 2014

Research study recruiting relapsing remitting multiple sclerosis patients

The patient and public involvement (PPI) team based at Imperial College London are conducting a study to understand which benefits and risks of treatment are most important to you. This is part of a research study called IMI PROTECT (http://www.imi-protect.eu/).

We would like to invite you to complete a short survey. The survey aims to understand your preferences for some of the benefits and risks of treatments for relapsing remitting multiple sclerosis. If you choose to take part, you will be asked to consider different treatment outcomes and compare them against one another.

The results of this study will be used by regulators to help them understand how patients feel about certain benefits and risks. It will also help them to decide which treatments should be made available for relapsing remitting multiple sclerosis. Additionally, the survey may provide useful information for new drugs to be developed which better meet your preferences.

Your participation will be kept anonymous and confidential.

Many thanks,

The Patient and Public Involvement team

INSTRUCTIONS

There are three sections in this survey. They are:

Section 1: Glossary Section 2: Questions Section 3: Feedback

Section 1 lists and describes the outcomes of treatment that you will be asked to consider during the study. In Section 2 you will be presented with pairs of made-up "treatments" with varying characteristics and asked to choose between them. This will allow us to value your preferences for different outcomes of treatment. Lastly, Section 3 will ask you for your feedback on this survey and how you think we can make it better.

Please note that there is not a "right" or "correct" answer to any of the questions.

QUESTIONNAIRE

DEMOGRAPHIC INFORMATION

All of the questions on this page are optional.

Q0.1 What is your gender? (Please tick one)

Male
Female
Prefer not to say

Q0.2 How old are you? (Please tick one)

18 to 29 years old
30 to 39 years old
40 to 49 years old
50 to 59 years old
60 years old and above
Prefer not to say

Q0.3 What is your educational level? (Please tick one)

Completed the legal part of school and the 1 st level of exams (age typically around 16, e.g. GCSEs)
Completed school and the higher level exams (e.g. A levels)
Completed some kind of third level education, e.g. university, technical college, etc. (e.g. Bachelor's degree)
Completed university and some kind of post graduate education (e.g. Master's degree)
Prefer not to say

Q0.4 Which type of multiple sclerosis do you have? (Please tick one or more)

Relapsing remitting multiple sclerosis
Secondary progressive multiple sclerosis
Primary progressive multiple sclerosis

Q0.5 When did you first experience symptoms of multiple sclerosis? (Please fill the blanks)

_____ years and _____ months

Q0.6 Would you like the results of the study to be emailed or posted to you? (Please tick one)

	Yes, emailed
	Yes, posted
	No

If you ticked "Yes", please can you provide us with either your email address if you would like the results emailed, or your address if you would like the results posted:

Q0.7 Would you consider participating in a focus group to further explore how you value the effects of multiple sclerosis treatments? Details are provided in the information sheet.

Yes
No

If you ticked "Yes", please can you provide us with your name and either your email address or telephone number so that our researchers can contact you.

SECTION 1: GLOSSARY

The questions in Section 2 are going to ask you about your preferences for certain treatment outcomes: number of relapses, disability progression, PML, mild allergic reactions, serious allergic reactions and depression. Before you begin, we would like to describe to you the terms we will be using, and what we mean when we use them.

DESCRIPTION OF OUTCOMES

Number of relapses

A relapse is defined by "the appearance of new symptoms, or the return of old symptoms, for a period of 24 hours or more – in the absence of a change in core body temperature or infection" (Source: MS Society). Medical staff might call relapses things like attack, flare-up, exacerbation, acute episode or clinical event. Symptoms you have experienced before, or perhaps grown used to dealing with, might appear in a different part of the body.

In relapses, symptoms usually come on over a short period of time – over hours or days. They often stay for a number of weeks, usually four to six, though this can vary from very short periods of only a few days to many months.

Relapses can vary from mild to severe. At their worst, acute relapses may need hospital treatment, but many relapses are managed at home, with the support of the GP, MS specialist nurse, and other care professionals.

Symptoms which come and go can sometimes be considered a relapse – they don't always have to be continuous. For example, some people experience a shock-like sensation when they bend their neck. This can be considered a relapse if it occurs every time they bend their neck for at least 24 hours.

The relapse figures used in this study refer to the number of relapses experienced by an average patient over a period of two years.

Disability progression

One way of measuring disability progression in MS is the EDSS: Expanded Disability Status Scale).

The EDSS Score is a 10-point scale to quantify disability in multiple sclerosis and to monitor changes in the level of disability over time.

The EDSS score is based around the following 8 symptoms:

- weakness or difficulty moving limbs
- a loss of coordination or tremor
- issues with speech, swallowing, or your eyes darting around (nystagmus)
- numbness or loss of sensations
- issues with bowel and bladder function
- issues with visual function
- issues with certain mental functions

• issues with other functions

In this study, we illustrate each treatment's effect on disability progression by reporting the number of patients (out of a group of 1000) whose EDSS score increases by at least one point over a two-year period.

SIDE EFFECTS

The outcomes listed below are all possible side effects of multiple sclerosis treatments, although some are very rare and many are unique to a particular treatment rather than being shared by all treatments.

In the next section we will ask you to compare treatments based on the number of patients who experience these effects, out of a group of 1000 patients overall. You will be asked to put this information together with the relapse and disability progression figures described above in order to come to an overall decision about which treatment you think is best.

What are the symptoms?	How long do they last for?	Can the symptoms be treated?		
PML				
PML is a viral brain infection. It can cause severe neurological symptoms, such as headaches, memory loss, changes in mental status, speech and vision difficulties, loss of strength, limb weakness, seizures, partial paralysis and loss of coordination.	Patients do not recover from PML; the symptoms rapidly worsen and usually lead to severe disability (e.g. permanent neurological damage) or death.	PML requires immediate medical attention and hospitalisation. There is no known treatment cure for PML.		
Serious allergic reactions				
Serious allergic reactions affect the whole body. Symptoms may include difficulty breathing, extremely low blood pressure, loss of consciousness and shock.	Serious allergic reactions usually take place two hours after the start of treatment but can happen at any time after receiving treatment. Depending on the type of serious allergic reaction, there may be full recovery or the reaction could be life-threatening and fatal.	Serious allergic reactions require immediate medical attention and hospitalisation.		

Mild allergic reactions					
The symptoms of mild allergic reactions may include: hives and/or rash, itching, trouble breathing and/or wheezing, chest tightness and/or chest pain, heart palpitations (e.g. heartbeats which feel like they are fluttering or pounding), dizziness, chills, nausea, flushing of skin (skin is red and/or feels warm), low blood pressure, anxiety, sweating, shaking or shivering.	These reactions can happen immediately or within a few hours of receiving treatment. The symptoms do not usually cause any problems and pass quickly. In some cases they can last for as long as thirty minutes.	Some mild common allergic reactions can be prevented on treatment days by taking over the counter medicines (e.g. paracetamol, ibuprofen) available from a pharmacist or other medicines which your doctor may prescribe.			
Depression					
Symptoms of depression may include feeling hopeless or feeling bad about oneself, and/or thoughts of hurting oneself and/or suicide.	Depression can occur as part of experiencing MS, and may be worsened by the treatment.	If depression is experienced the treatment is stopped and psychiatric treatment is necessary e.g. cognitive behavioural therapy and/or antidepressants prescribed by a doctor.			

SECTION 2: QUESTIONNAIRE

INSTRUCTIONS

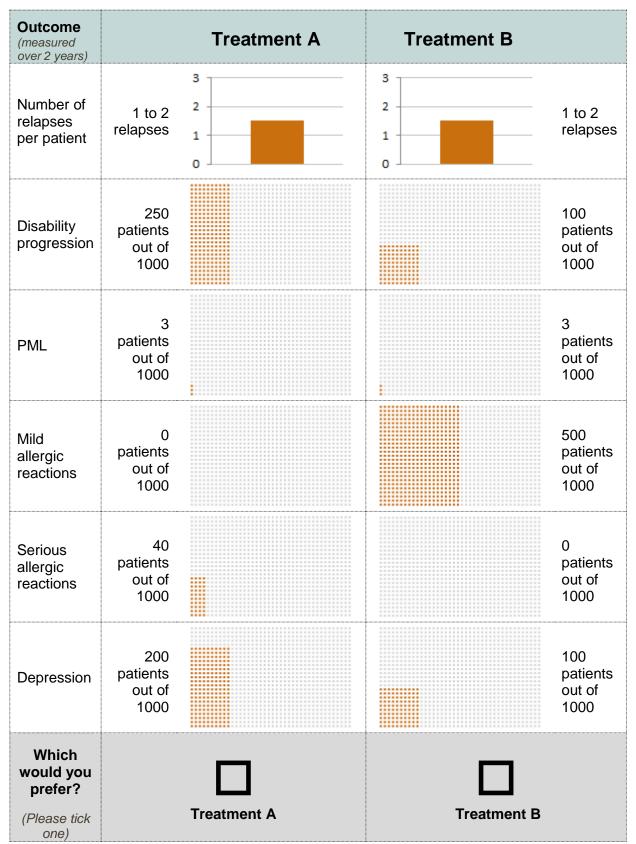
The next set of questions will describe a series of imaginary scenarios where two non-real treatments for relapsing remitting multiple sclerosis are described to you. Then, we ask you to imagine that you have relapsing remitting multiple sclerosis and have an option of receiving one of the treatments. We would like to know which treatment you would prefer.

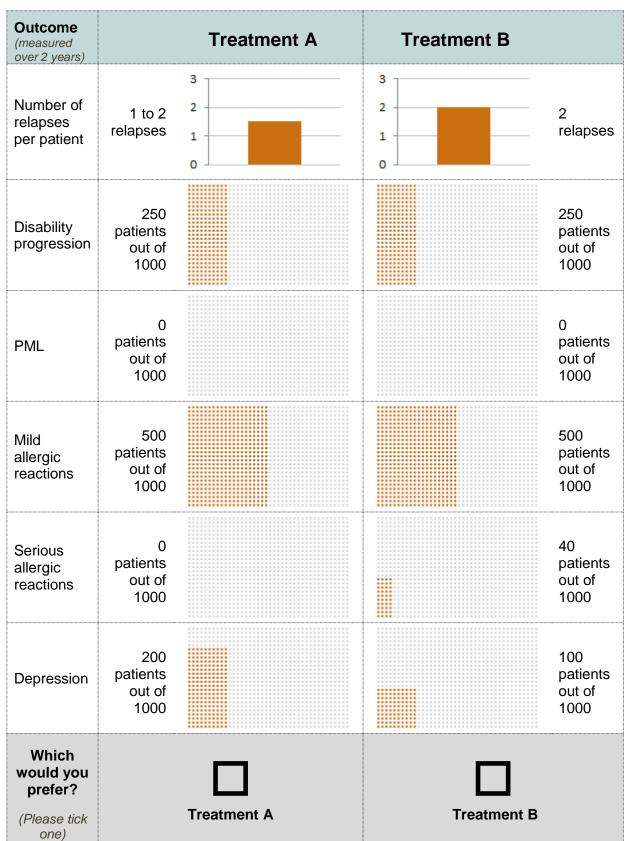
Each choice requires you to consider two treatments (Treatment A and Treatment B), which differ by how many relapses the average patient experiences and how people on average out of 1000 experience disability progression, PML, mild allergic reactions, serious allergic reactions and depression. Each of these outcomes was described in the previous section.

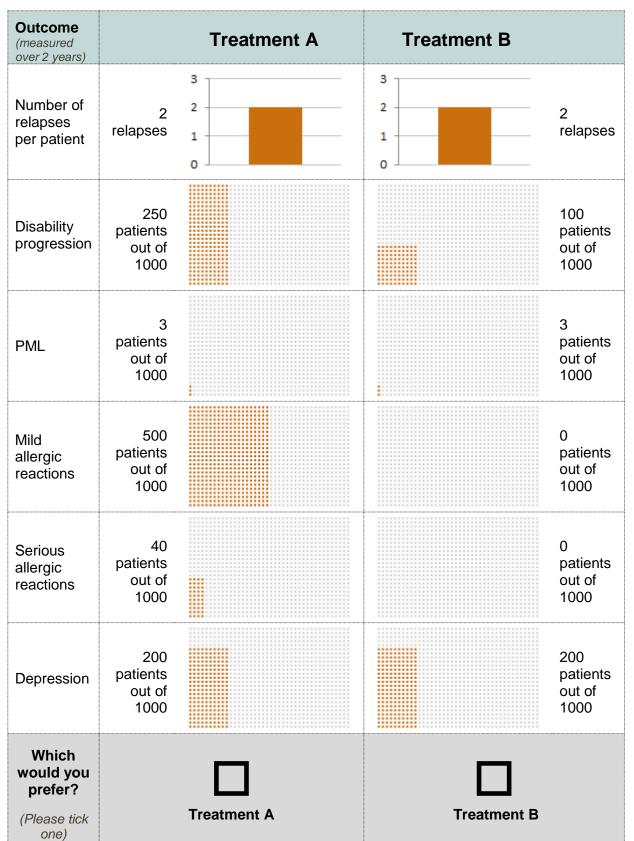
The differences between the treatments are hypothetical (the treatments are imaginary), and your selection of treatment will not affect or alter any current medical care you may be receiving.

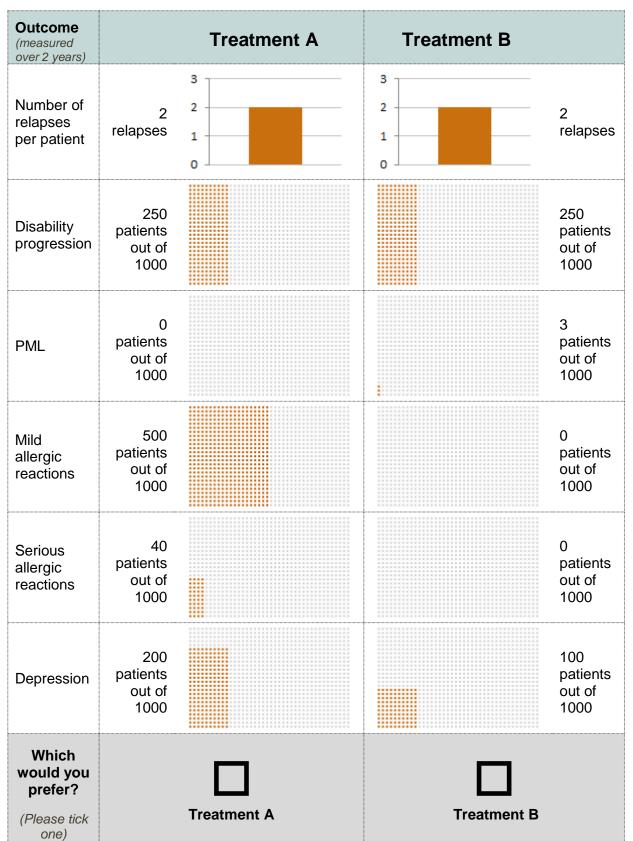
Please note that there is not a "right" or "correct" answer for any of these choices in the scenarios. We simply ask you to select the treatment that you prefer the most.

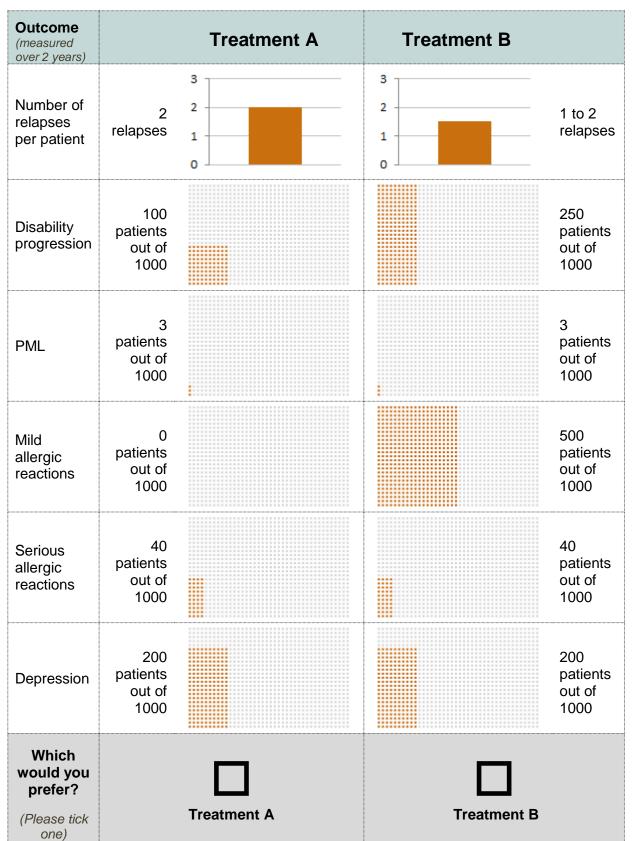
We would like you to answer as many of these questions as you can so that we can learn as much as possible from this study. There are eighteen questions in total. However, if you prefer not to answer all eighteen questions, you may choose to skip ahead to the next section at any point after question nine. We do need a substantial amount of data for the study and so we kindly ask all participants to complete at least the first nine questions.

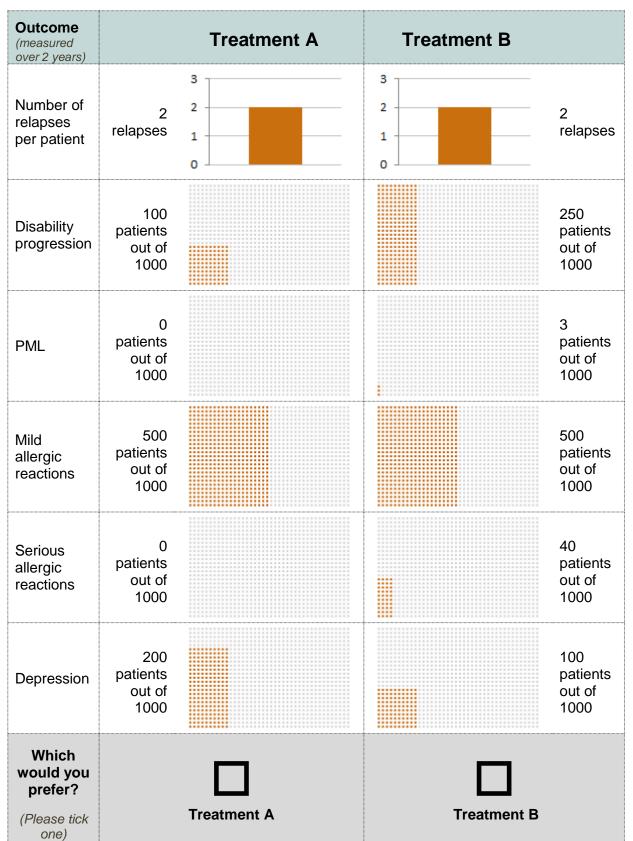


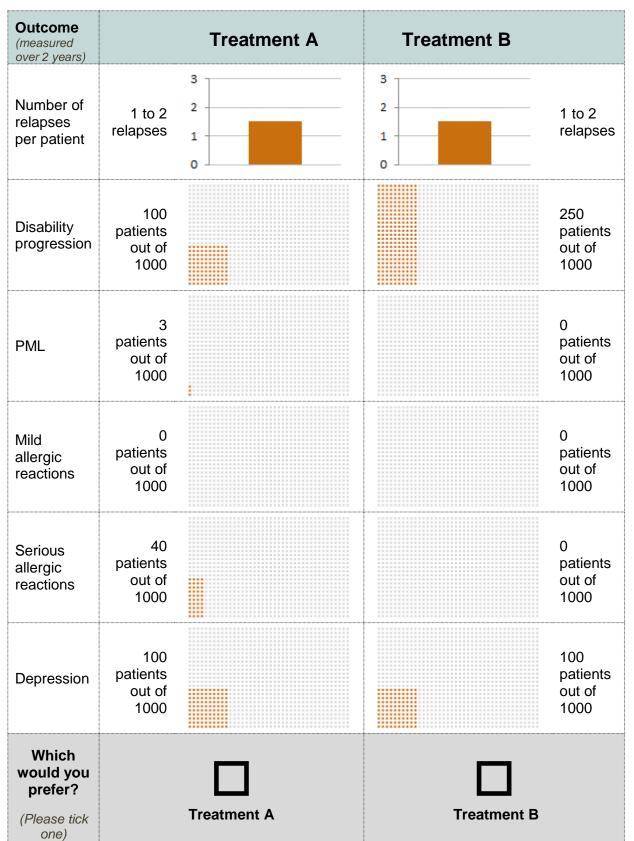


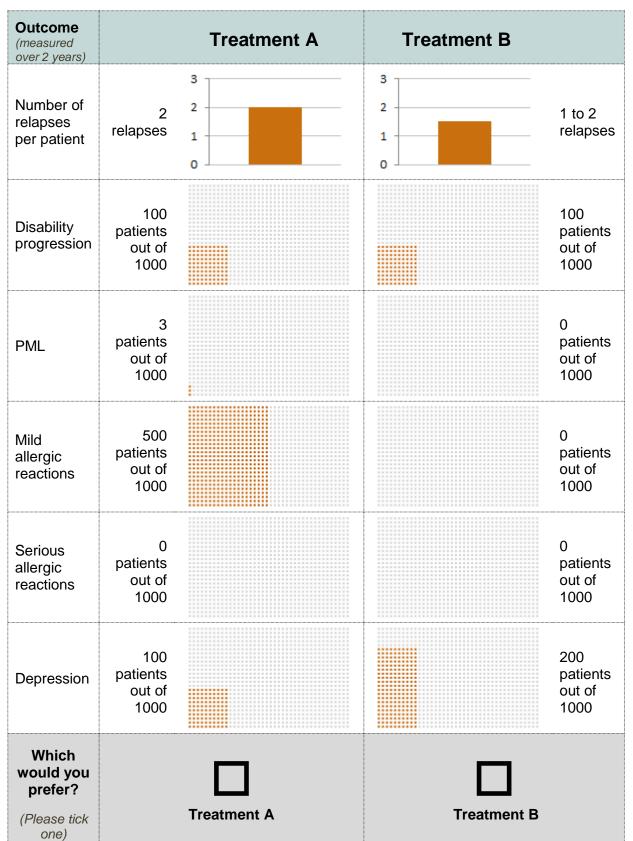


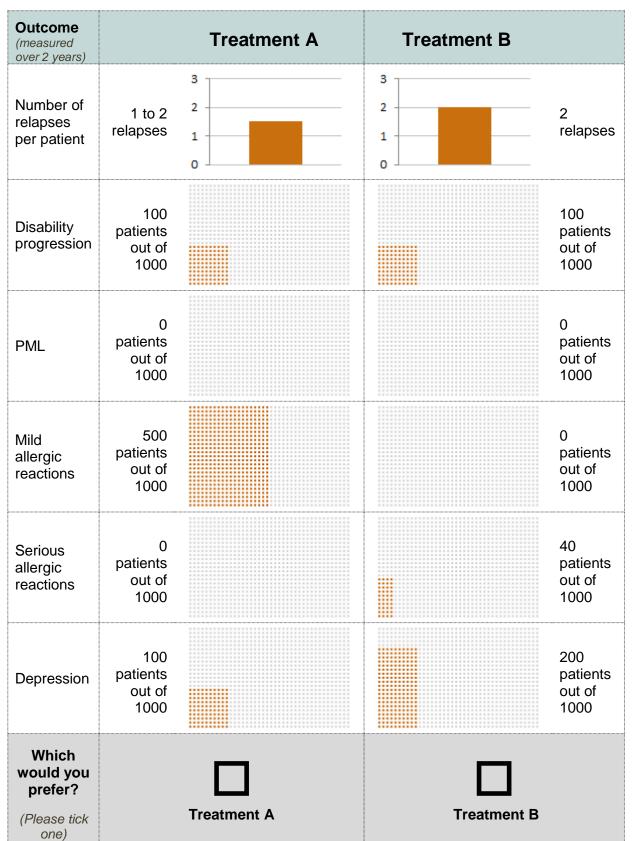






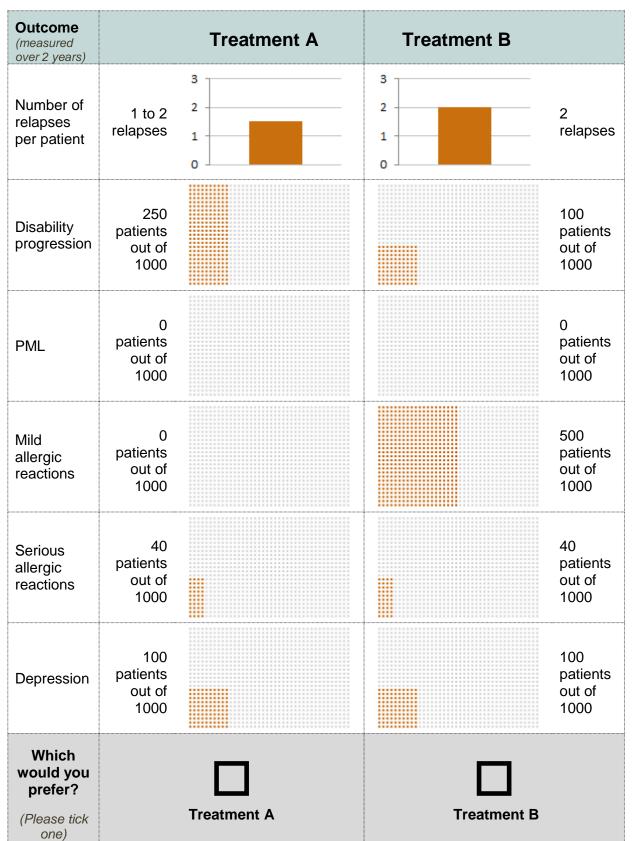


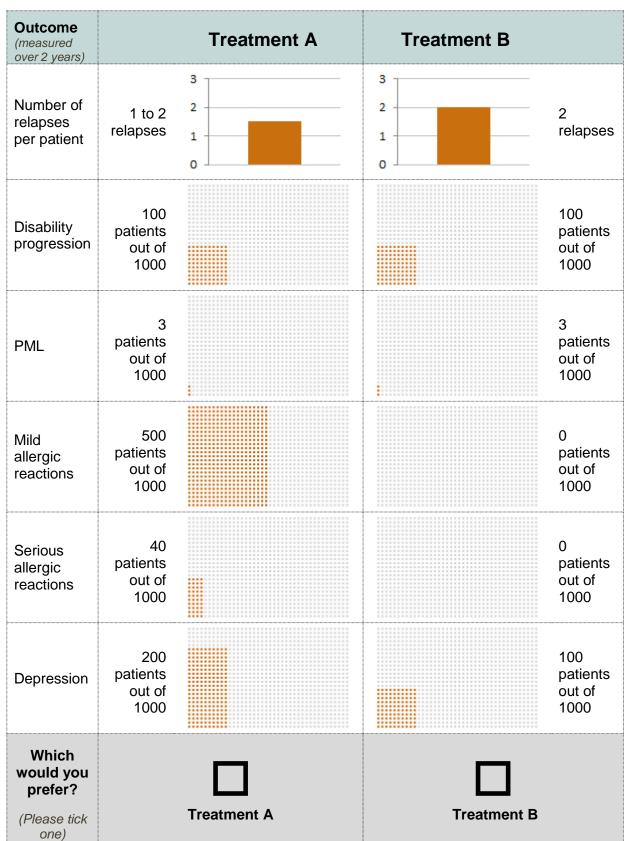


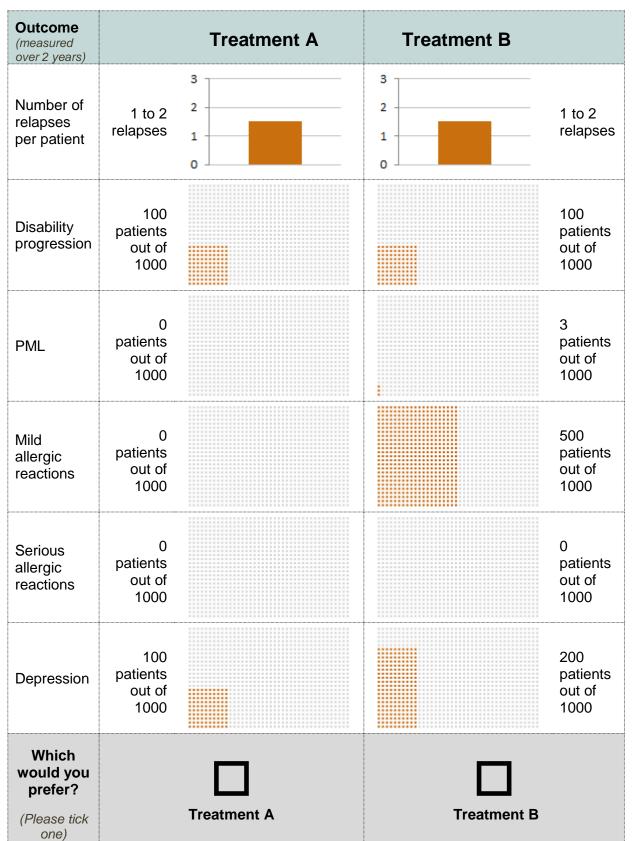


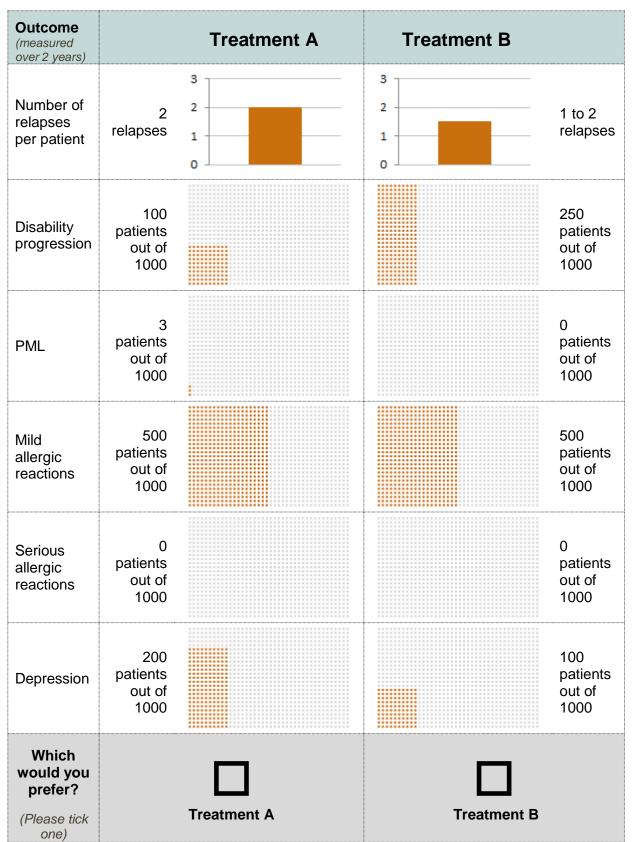
OPTIONAL QUESTIONS

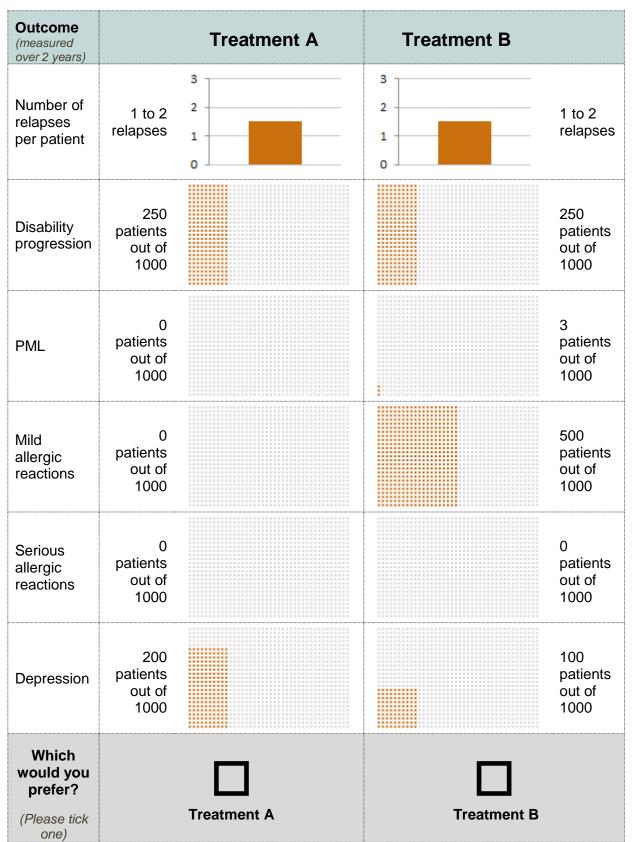
The following nine questions are optional. If you would prefer not to spend any more time on the survey, please skip ahead to the next section (page 29). If possible, however, we would prefer you to complete the following nine questions, or as many as you can.

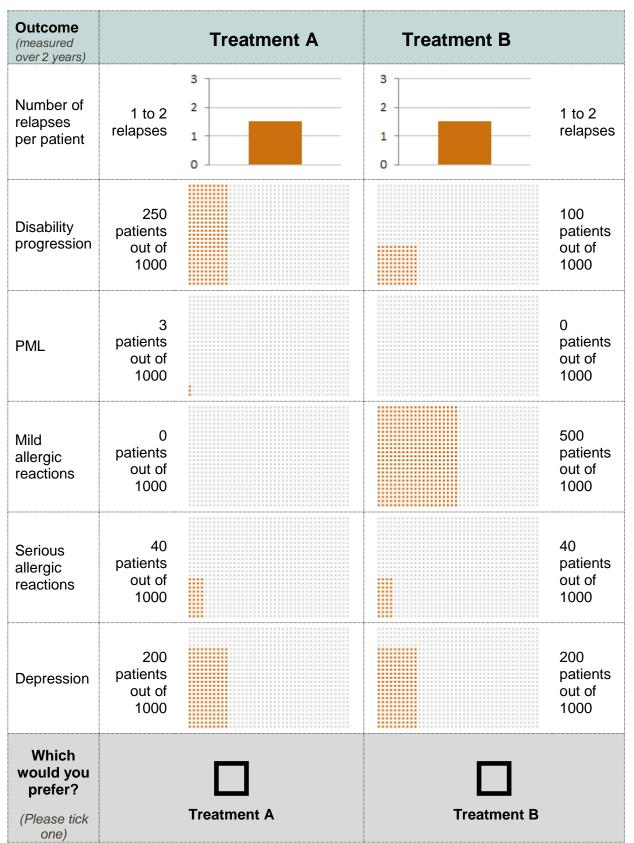


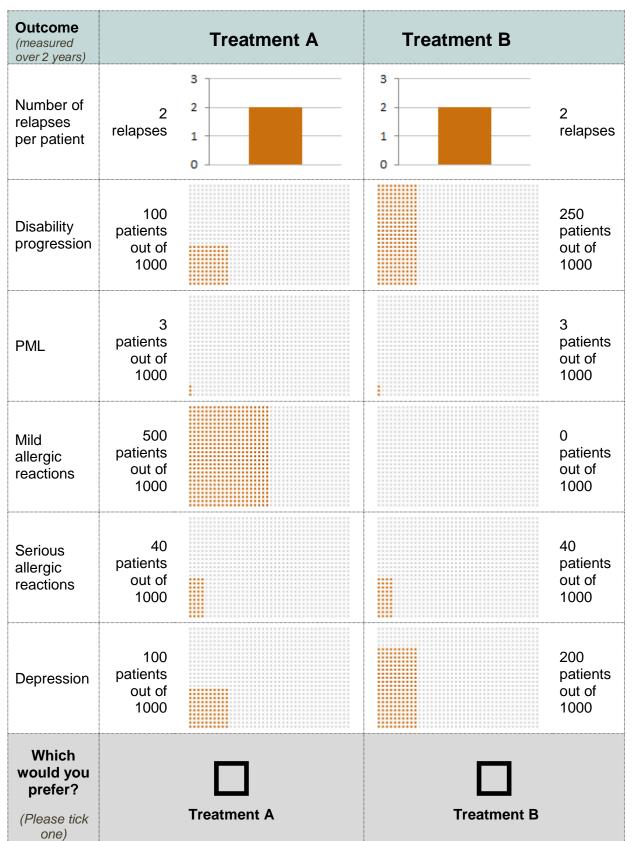


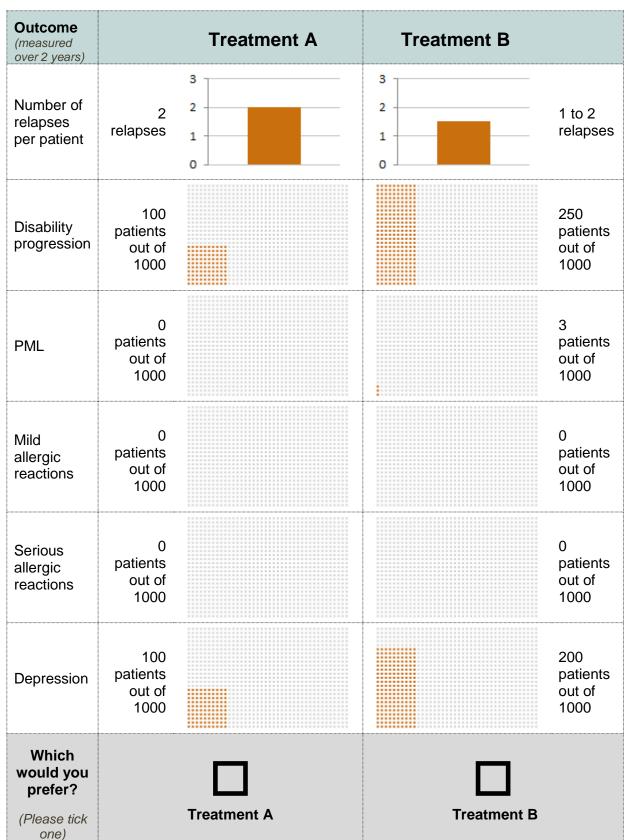


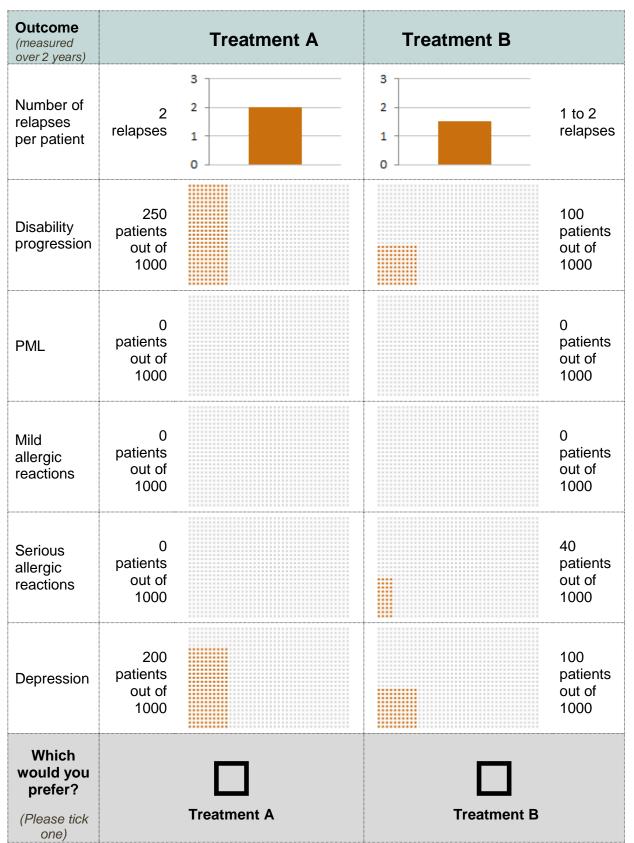












SECTION 3: FEEDBACK

This section asks you for your feedback. Your responses to this section can help us to consider how we can make this survey more appropriate or relevant for your needs in the future.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
"It was easy to make comparisons between the outcomes."					
"The questions adequately reflect the aspects of relapsing remitting MS that I feel are important."					
"Enough information was provided, in a clear and understandable format, to enable me to answer the questions."					
"I would be happy to take part in similar surveys in the future."					

Please provide any additional comments you may have in the space below:

Thank you for your time and help.