

**DOMINO Patient and Public Focus Group
26th September 2008 at the RICE Centre, Bath**

In September, 15 carers of patients living with dementia, and some patient themselves, met to share ideas about clinical research. They discussed how to increase recruitment of patients into dementia research, and thought about positive ways to boost interest in an important study called DOMINO.

There was a good mix of different dementia carers' points of view, and in addition some helpful "external" perspectives from two patients with motor neurone disease and Parkinson's disease. There were suggestions of possible ways to improve recruitment, although some ideas are not applicable at a local level, and would need national consideration.

DeNDRoN Nurse, Katie Stocker, outlined the DOMINO Study

DOMINO is backed by the Alzheimer's Society and the Medical Research Council. The aim is to recruit 850 people with Alzheimer's who have been taking donepezil but have reached the point where NICE guidance indicates stopping it. Patients agreeing to be in the study would be in one of four groups, and wouldn't know which they are in: **1)** continuing treatment with donepezil, **2)** memantine, **3)** a combination of these two drugs, or **4)** a 'placebo'. The outcomes of the groups will be compared in terms of cognition, quality of life and any move in to a care home.

Group Discussion of the DOMINO study

To start with, the NICE guidance was discussed in general. Participants who had been in a caring role for someone with severe Alzheimer's disease were strongly against the NICE guidance to remove donepezil, because it is at a particularly difficult stage of the illness when it is essential to avoid unnecessary disruptions.

One carer shared their experience of the donepezil dose being reduced which led to a significant deterioration in their relative's behaviour. When the donepezil dose was increased again, her behaviour progressively returned to the previous level.

One carer shared their experience of the person they provide care for being on a combination of memantine and donepezil already. They said that it seems very helpful in managing distressing behaviours. However, the carers of patients just on donepezil expressed that they simply would not want to risk upsetting what is a manageable situation. Even with the ability to go back onto the pre-study dose of donepezil if the patient begins to decline on the study drug, the carers in the group would not be willing to put up with the decline and recovery time.

It was also suggested that the results of the trial may be "skewed" and unrepresentative, if the only patients taking part are those who have had their donepezil prescription removed as it no longer seems to be helping.

Some clinicians follow NICE guidelines more firmly than others. As donepezil is often available either from clinicians who do not follow the NICE NHS prescription guidelines, or privately for those who can afford it, the study will be difficult to conduct as some people will not risk being in the placebo arm if they have access to the medication.

Doctors and nurses therefore need to properly address these issues in discussions with potential DOMINO study participants, including stressing that DOMINO provides a 3 in 4 chance of remaining on an active medication.

It was suggested that DeNDRoN's best focal point for recruiting more patients might be to concentrate on the clinicians who are firmly following the NICE guidelines.

Other Thoughts and Suggestions raised

Placebo: A suggestion was made to remove the placebo arm from the study, even at this late stage, if necessary. The group did acknowledge that this would provide far less evidence for the use of donepezil in the more advanced stages of the disease as it would then only be a comparison of medications rather than comparing disease progression with and without medication.

GPs: It was suggested that a wider catchment of patients could be achieved by asking GPs to refer as well as clinicians in memory clinics.

Raising awareness: DeNDRoN staff reported that they frequently visit clinicians and gives presentations to staff, but these appear to have very little impact on recruitment rates.

The group hoped that going directly to patient groups to increase local awareness of research and research opportunities would help. Patient and public involvement events – such as this discussion – could raise awareness of research opportunities among targeted populations.

Register: Calls for a register for people with dementia to express their interest in future research was well received.

Overall Impressions of the Day

The patients living with dementia who attended did not contribute. One couple left early due to the patient becoming agitated, and one carer stated that she would have liked to come alone so she could express her views more openly. It may be best in future to have separate groups for carers and patients.

Inclusion of two patients living with other neurodegenerative diseases added a useful dimension, and is worth trying again.

All the carers who attended contributed a lot, and all felt that the discussion was successful in identifying some key issues which affect the level of recruitment to DOMINO.