

# Trial of Option Grid for Arthritis of the knee (TOGA): easy to use shared decision making tools for disadvantaged groups

<b>Submission date</b> 12/03/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 21/03/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/10/2018	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Option Grids are one-page evidence-based summaries of the available condition-specific treatment options, listing patients frequently asked questions. They are designed to be brief and accessible enough to support better communication between patients and doctors during routine consultations. This study aims to find out whether an Option Grid for osteoarthritis of the knee (OA of the knee) aids in shared decision making (SDM), and to explore the use of Option Grids by patients with language difficulties or poor medical knowledge.

### Who can participate?

Patients over the age of 18 with osteoarthritis of the knee referred to a specialist musculoskeletal clinic in Oldham (Pennine MSK Ltd) can participate.

### What does the study involve?

We will collect information from two groups of people: one group will be given an Option Grid by their doctor in their appointment; the other group will not be given an Option Grid by their doctor. We will then compare the information we collect from both groups to see if there are any differences.

### What are the possible benefits and risks of taking part?

The information we gain from this study may help us provide future patients with osteoarthritis of the knee with better information about the available treatment options. Apart from the time and effort required to take part in the study, we foresee no difficulties or risks to taking part.

### Where is the study run from?

The study is being run by researchers in the School of Medicine at Cardiff University, UK.

### When is the study starting and how long is it expected to run for?

Recruitment to the study started in September 2013 and is expected to finish in March 2014.

Who is funding the study?  
The study is being funded by the Bupa Foundation, UK.

Who is the main contact?  
Dr Fiona Wood  
wood@cardiff.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Fiona Wood

**Contact details**  
Institute of Primary Care and Public Health  
Cardiff University  
Neuadd Meirionydd  
Heath Park  
Cardiff  
United Kingdom  
CF14 4XN  
-  
wood@cardiff.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
SPON 1044-11

## Study information

**Scientific Title**  
Option Grids: easy to use shared decision making tools for disadvantaged groups a stepped wedge exploratory trial

**Acronym**  
TOGA

**Study objectives**  
It is hypothesised that levels of shared decision making (as measured by the OPTION tool) will be higher in consultations where an option grid is used by patients and clinicians.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

South East Wales LREC, 23/12/2011, ref.: 11/WA/0356

**Study design**

Stepped wedge exploratory trial

**Primary study design**

Interventional

**Secondary study design**

Non randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Osteoarthritis of the knee

**Interventions**

Six physiotherapists will sequentially join the trial and consult with six patients using usual care procedures. After a period of brief training in using the Option Grid, the same six physiotherapists will consult with six further patients using an Option Grid in the consultation. The primary outcome will be efficacy of the Option Grid in facilitating SDM as measured by observational scores using the OPTION scale. Comparisons will be made between patients who have received the Option Grid and those who received usual care. A Decision Quality Measure (DQM) will assess quality of decision making. The health literacy of patients will be measured using the REALM-R instrument. Consultations will be observed and audio-recorded. Interviews will be conducted with the physiotherapists, patients and any interpreters present to explore their views of using the Option Grid.

There is no randomisation. Patients are sequentially assigned to the next clinician who is either in the pre-intervention or post-intervention stage.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

The primary outcome is the efficacy of the Option Grid in facilitating Shared Decision Making as measured by observer scores using the OPTION scale.

### **Secondary outcome measures**

Secondary analysis will explore:

1. The quality of decision making as measured by the Decision Quality Measure (DQM); treatment decision at 3 months post consultation
2. The extent to which the intervention has reached disadvantaged groups as measured by the literacy of participants utilising the REALM-R instrument and socio-demographic variables
3. A qualitative investigation will explore the acceptability of the option grid to patients and physiotherapists and how these tools are used in consultations where interpreters are present

### **Overall study start date**

01/09/2012

### **Completion date**

01/03/2014

## **Eligibility**

### **Key inclusion criteria**

Patients over the age of 18 with osteoarthritis of the knee who are referred to the Pennine MSK specialist musculoskeletal centre.

Clinicians will be employed by Pennine MSK.

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

72

### **Key exclusion criteria**

There are no specific exclusion criteria. We will only exclude those patient participants who are unable to communicate adequately in English (as judged by their ability to understand the participant information sheet) and where we do not have interpreters or family members available to assist their participation.

### **Date of first enrolment**

01/09/2012

**Date of final enrolment**

01/03/2014

## Locations

**Countries of recruitment**

United Kingdom

Wales

**Study participating centre**

**Institute of Primary Care and Public Health**

Cardiff

United Kingdom

CF14 4XN

## Sponsor information

**Organisation**

Cardiff University (UK)

**Sponsor details**

c/o Mrs Kathryn Prittard-Davies

Research and Commercial Division

30-36 Newport Road

Cardiff

Wales

United Kingdom

CF24 0DE

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DaviesKP2@cardiff.ac.uk

**Sponsor type**

University/education

**ROR**

<https://ror.org/03kk7td41>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

BUPA Foundation (UK)

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	07/04/2014		Yes	No
<a href="#">Results article</a>	results	01/04/2016		Yes	No
<a href="#">Results article</a>	results	01/12/2017		Yes	No
<a href="#">Results article</a>	results	01/02/2018		Yes	No