

# TARVA Newsletter

RANDOMISED CLINICAL TRIAL

**TARVA is a clinical trial for patients with ankle arthritis who are considering surgery**

TARVA stands for Total Ankle Replacement Versus Arthrodesis (fusion), which are the two main surgical treatments for ankle arthritis.

Surgery type will be allocated to patients at random. For one year following surgery, the success of each operation will be assessed and compared in terms of each patient's ankle function and quality of life.



To learn more about the TARVA Trial please visit our website [www.anklearthritis.co.uk](http://www.anklearthritis.co.uk) or follow us on Twitter @TARVA\_Trial

## Funding

This trial has been funded by the National Institute of Health Research (NIHR) Health Technology Assessment (HTA) Programme - HTA Project: 12/35/27



## News

### 12 patients randomised and 11 operations performed\*

Eleven recruited patients have now had ankle surgery as part of the trial. In this newsletter you can read about the first TARVA patient's experiences, and get the chance to see a 'GoPro®' ankle surgery patient blog (page 2). \*as of end July 2015



### Seven sites actively recruiting

We are delighted that Newcastle's Freeman Hospital, Royal Derby Hospital, and Guildford's Royal Surrey County Hospital are now recruiting patients alongside the Royal National Orthopaedic Hospital, Aintree University Hospital, Sheffield's Northern General Hospital, and Wrightington Hospital.



### TARVA Twitter

@TARVA\_Trial over 1000 followers. Follow us...

### TARVA in Frontline Magazine

TARVA soon to appear in a leading magazine for physiotherapists.



### TARVA presented at National Bigfoot meeting

Andy Goldberg, TARVA Chief Investigator, was invited to speak about the trial as part of the International Faculty at the prestigious Bigfoot meeting, held at the Royal College of Surgeons in London in June 2015.



The meeting is the world's largest international meeting of experts in foot and ankle orthopaedic surgery with more than 20 distinguished international faculty members and 300 delegates from over 30 countries.

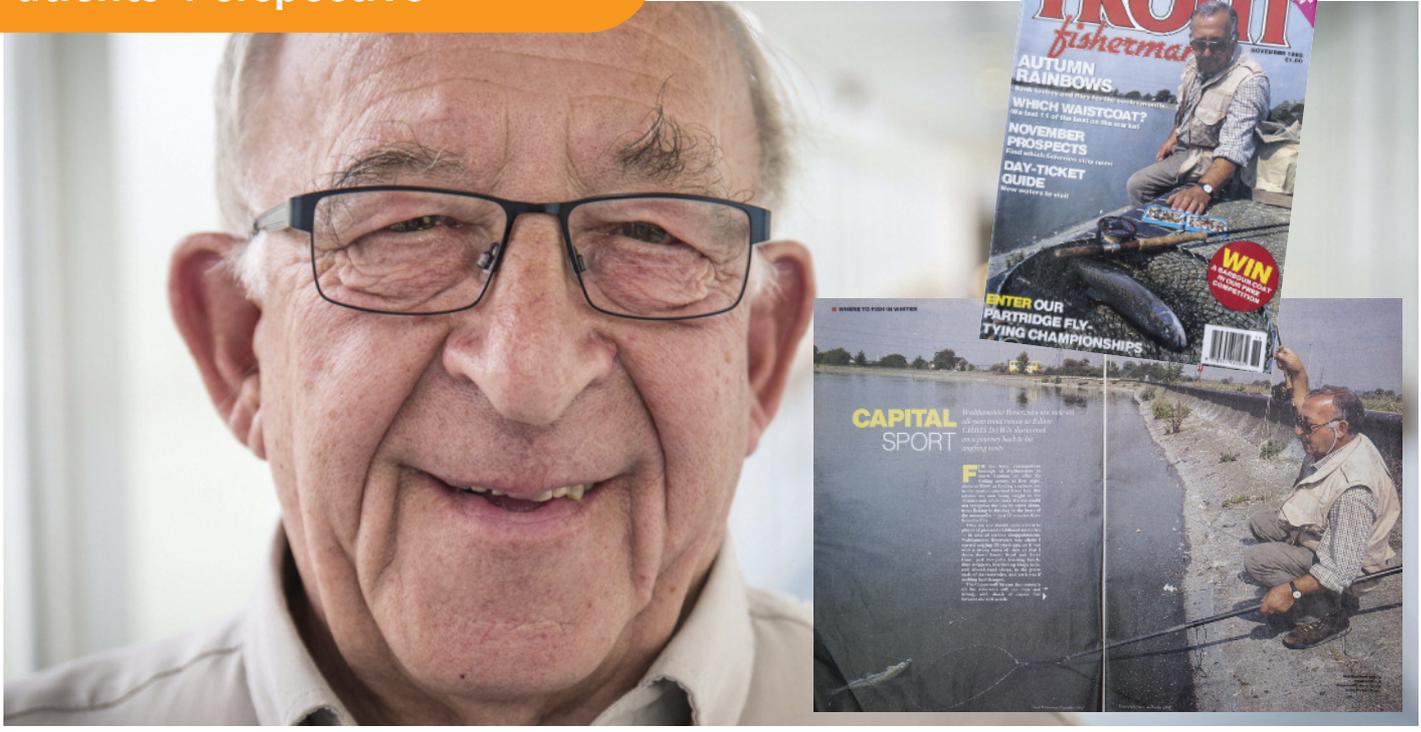
### RNOH Clinical Nurse Specialist, Karen Alligan, nominated for Nursing Times Awards 'Nurse of the Year'

Karen is one of eight nurses nominated. Results to be announced at a Gala Dinner at Grosvenor House, London on 12th November 2015.

### Early TARVA recruitment data to be presented at International Clinical Trials and Methodology (ICTM) Conference

The conference will be held in Glasgow, 16-17th November 2015.

**TARVA from the Patients' Perspective**



**The first patient to undergo surgery as part of the TARVA trial, former England fisherman Sidney Gardiner, tells us about how his life has changed since having ankle surgery:**

I was a carer for my wife for a couple of years and I knew I needed to have my left ankle treated but I kept putting it off. I was in such pain I could hardly walk. I had had my other ankle treated previously also, so I knew I needed surgery. I had injections and took a lot of pain killers but it was so bad. I was using the stair lift at home to get upstairs.

I heard Mr. Goldberg talking about TARVA on Radio 4 and then I saw an article in Mail On Sunday. My GP

referred me to Stanmore and I saw Mr. Goldberg and all the lovely staff and the process was made very simple.

It was quite easy for me to let the computer decide which operation I was going to have and it's all been brilliant. I am back to fishing and tending my garden, it's given me a new lease of life and I have lost weight. I have also given up the stair lift now as it's much quicker to walk.

**World's first ankle surgery blog launched on TARVA website:**

We were delighted when **David Shaw**, one of the first TARVA patients to be randomised and undergo surgery, offered to write a blog of his experiences. Visit the **TARVA website** to read about his fascinating and detailed personal journey including his physical and emotional preparation for surgery.

**A highly-recommended read for anyone considering ankle surgery, their families and friends.**

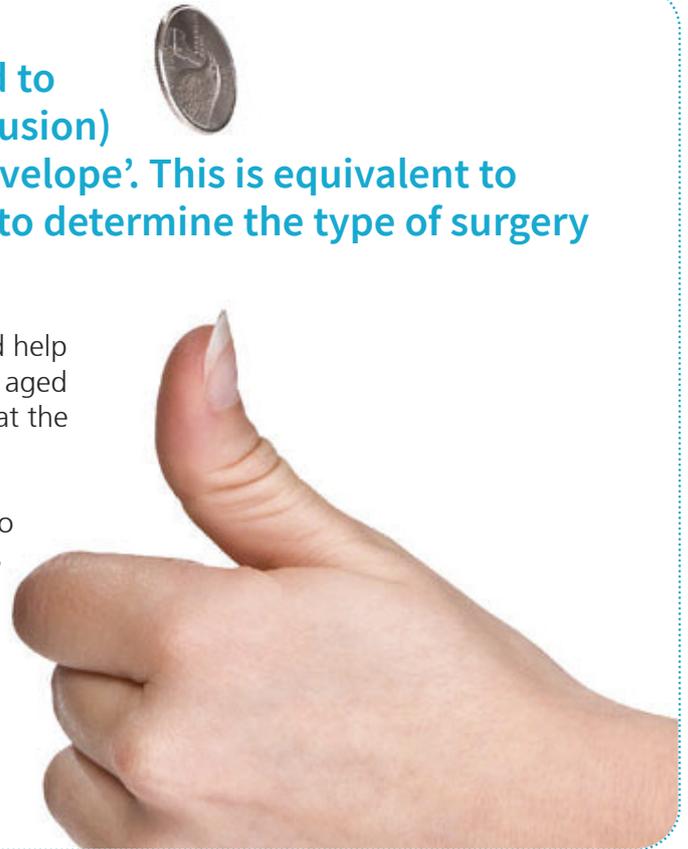


## Randomisation explained

In TARVA, patients are randomly allocated to ankle replacement or ankle arthrodesis (fusion) by a computer program called 'Sealed Envelope'. This is equivalent to using the toss of a coin or the roll of a die to determine the type of surgery that each patient will receive.

Randomisation in clinical trials is essential to prevent bias and help ensure that patients in the trial are representative of patients aged 50 to 85 who require surgery for ankle arthritis, ensuring that the groups are directly comparable.

By randomly allocating patients with ankle arthritis to the two different surgery types in TARVA we can be sure that groups are balanced in the characteristics of patients allocated to each procedure so that comparisons between them are fair. In this way, we can be confident that differences between groups are due to the choice of surgery, TAR or arthrodesis, rather than to differences between the patients.



## Meet the Independent Data Monitoring Committee

An Independent Data Monitoring Committee (IDMC) is the only oversight body that has full access to accumulating data. The IDMC is responsible for safeguarding the interests of trial patients, monitoring the accumulating data and making recommendations to the Trial Steering Committee on whether the trial should continue as planned. Here we meet the Chair and committee members:



**Professor Justin Cobb,**  
**TARVA IDMC Chair**

Professor of Orthopaedic Surgery, Imperial College London



**Professor Mike Hurley,**  
**TARVA IDMC Member**

Professor of Rehabilitation Sciences, St Georges University of London and Kingston University



**Professor Linda Sharples,**  
**TARVA IDMC Member**

Professor of Statistics, Leeds Clinical Trials Research Unit

## The TARVA Statistician



**Simon Skene** is leading the TARVA statistical analysis at the UCL Comprehensive Clinical Trials Unit.

Simon has more than 15 years' experience, combining research and teaching in Statistics at the Open University and Birkbeck College. He also has consultancy experience within the pharmaceutical industry and is a fellow of the Royal Statistical Society.

## Recruitment Update

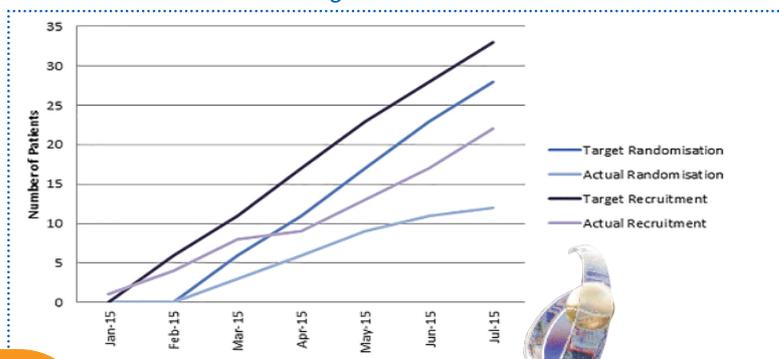
A big thank you to all of our sites for checking whether their ankle arthritis patients considering surgery are eligible to take part and for providing the study information, and to our first participants for taking part and contributing to this valuable research.

The table and graph on the right show how the monthly number of participants is growing as new centres are opening for recruitment. This early data will be used to help the Research Team to determine whether it will be possible to reach our target of 328 patients and what we will need to do to achieve it.

### TARVA cumulative recruitment figures

| Month         | Patients eligible for TARVA | Patients recruited | Patients randomised* (TAR / fusion) | Number of operations performed |
|---------------|-----------------------------|--------------------|-------------------------------------|--------------------------------|
| January 2015  | 10                          | 1                  | 0                                   | 0                              |
| February 2015 | 19                          | 6                  | 0                                   | 0                              |
| March 2015    | 29                          | 11                 | 3                                   | 0                              |
| April 2015    | 42                          | 12                 | 6                                   | 4                              |
| May 2015      | 47                          | 13                 | 9                                   | 6                              |
| June 2015     | 63                          | 18                 | 11                                  | 8                              |
| July 2015     | 73                          | 22                 | 12                                  | 11                             |

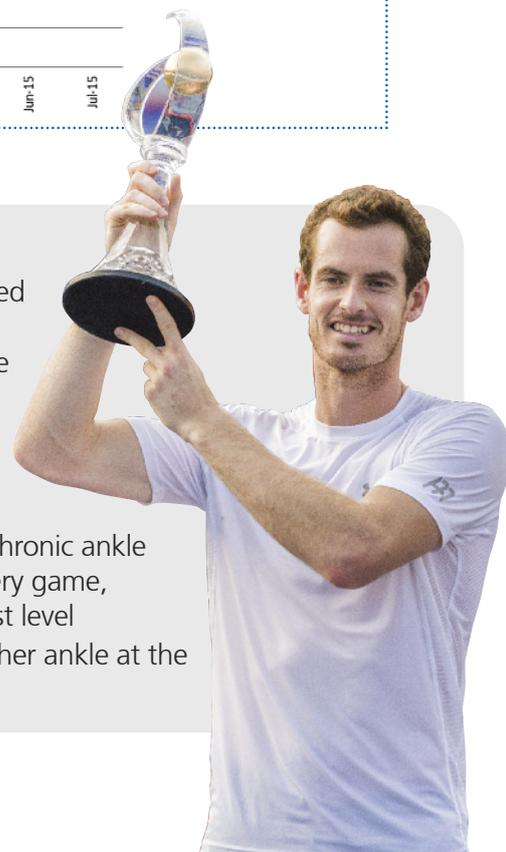
\* There is a delay between recruitment and randomisation as patients need to have an ankle MRI scan which must be graded before their treatment is allocated.



## Celebrities in the Spotlight

Even celebrities and top athletes aren't immune from ankle injury. After all, twisted ankles are the most common injury amongst athletes and comprise 40% of athletic injuries. Models often suffer bruised feet, heels and ankles from squeezing into uncomfortable, ill-fitting shoes on the catwalk. Bruises, sprains and cuts are worryingly common at Fashion Week shows.

- **Golfer Rory McIlroy** sustained a ruptured ankle ligament playing football with friends in July 2015 taking him out of the British Open
- **Singer Jessie J** had to have ankle surgery in 2013 after falling off a stage during rehearsals at Wembley Stadium
- **Tennis star Andy Murray** has battled chronic ankle problems and wears ankle braces for every game, despite which he competes at the highest level
- **Model Linsey Wixon** fell and sprained her ankle at the Paris fashion show earlier this year.



### Editorial team contact details

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**Mr Andrew Goldberg**  
Newsletter Advisor

**Mrs Marion Cumbers**  
Newsletter Patient Representative

If you have a story or case study you would like included in a future newsletter, please let us know at [tarvanewsletter@rnoh.nhs.uk](mailto:tarvanewsletter@rnoh.nhs.uk)

[www.anklearthritis.co.uk](http://www.anklearthritis.co.uk) @TARVA\_trial

### Coming in the next newsletter:

- 1) Recruitment update
- 2) Summary of the first six months (March – September 2015)
- 3) Meet a Research Nurse