

WORLD'S FIRST LONG-TERM STUDY TO SUPPORT TESTOSTERONE REPLACEMENT THERAPY (TRT) FOR MEN

The longest ever clinical study¹ of TRT concludes it could greatly enhance the lives of millions of men

Published today in the Journal of The Aging Male a study of over 2000 patients (attending the UK's Centre for Men's Health for testosterone treatment and spanning over 26 years) is the longest and most comprehensive research on testosterone to date – comprising over 4,500 years of treatment. The ground-breaking paper finds that current testosterone testing practices need to be urgently reviewed and will overturn undue concerns on the safety of TRT.

Professor Malcolm Carruthers, Chief Medical Officer at the Centre for Men's Health, comments: *"This study proves TRT's effectiveness in relieving the symptoms of thousands of men from across the UK, but most importantly supports the safety of testosterone treatment - even over prolonged periods. I believe that around 2million men in the UK could benefit from symptom relief, but outdated testing methodology and undue safety concerns have prevented the vast majority from receiving the treatment they need."*

Testosterone deficiency (TD) can devastate the health and wellbeing of men, also affecting their intimate relationships with their partners. The male patients, who had a mean age of 54, were identified as experiencing the symptoms of androgen deficiency or andropause. Typical symptoms include joint pain, night sweats, hot flushes, low libido, lack of morning erections, low mood and 'brain fog'. It is estimated that up to 2 million men in the UK could benefit from TRT^{2,3} – which equates to around 1 in 5 men over the age of 50 – while only 25,000 are getting it.

The ground-breaking paper finds that TRT can be safe and effective over extended periods. Some research has suggested that TRT could have a negative impact on certain aspects of health. However this new study of seven different kinds of TRT showed all to be equal in safety with either no change or improvements in key health parameters. For instance in cardiovascular risk factors, where a mild benefit in lowering cholesterol and diastolic blood pressure was observed. There was also no increase in incidence of prostate cancer.

Further, the paper argues that the current approach to diagnosing TD must be urgently reviewed, as it is leading to many men who could safely benefit from therapy going untreated, with significant ongoing health consequences. The research argues that there is currently excessive reliance on laboratory testing of total testosterone (TT) level in the blood and that a broader diagnostic approach is needed. In the study TD was diagnosed through assessing symptoms and medical history, alongside complex bloodwork analysis.

In the study there was no correlation between severity of initial symptom score and initial testosterone level. It is suggested in the paper that each man has a consistent healthy testosterone level individual to them. When a man's levels fall below this, he may develop testosterone deficiency symptoms even if his blood level of testosterone remains within 'normal range'⁴ that GPs and endocrinologists currently test for.

It is also suggested that the body can become resistant to testosterone, meaning it is unable to use the available testosterone in the blood as efficiently. This can also lead to symptoms, even when blood level of testosterone is in the 'normal range'.

Professor Carruthers adds: *"Contrary to orthodox theory, there is no threshold for testosterone levels. Resistance to the hormone could be caused by age, stress, obesity, alcohol intake or genetic factors. Our patients had a thorough clinical assessment with many more markers than simple TT – a medical history and most importantly their symptoms."*

When TRT was prescribed nearly all men benefited from an improvement. *"In most cases with complete resolution of their symptoms,"* adds Professor Carruthers. One patient, whose data I recorded in the study, has waived his right to anonymity to call on the NHS to review its current thinking on TRT. Ian Macdonald, 78, comments: *"I am one of the patients whose data has been included in a new research paper. I am pleased that the study has shown that TRT can be safe and hopefully doctors will be more open to this treatment for other men like me. I'm in excellent physical and mental shape and am eternally grateful for this treatment."*

The investigators conclude that, with careful, ongoing monitoring of safety parameters, TRT can be a safe, effective and economic treatment for men experiencing testosterone deficiency symptoms and health problems resulting from TD. However excessive emphasis on TT blood tests and unjustified health concerns are preventing many men from receiving TRT.

-ENDS-

Notes to editors:

We can provide on request:

- The full clinical paper
- The symptom checklist and questionnaire
- Additional commentary from other Key Opinion Leaders (KOLs)
- Interviews with Professor Carruthers and other KOLs
- Full patient stories and interviews

For further information please contact:

Lara Sutherland / Matthew Barnett

Beattie Communications

Lara.sutherland@onlybeattie.com / Matthew.Barnett@onlybeattie.com

0207 053 6019

References

1 Carruthers M, Cathcart P and Feneley M, *Evolution of testosterone treatment over 25 years: symptom responses, endocrine profiles and cardiovascular changes* (The Aging Male journal, 2015)

2 Carruthers M, Trinick TR and Wheeler MJ, *The validity of androgen assays* (The Aging Male journal, 2007); 10(3): 165-172

3 Carruthers M, *Time for international action on treating testosterone deficiency syndrome* (The Aging Male journal, 2009) 12(1):

4 NHS guidelines suggest a lower limit of 6-8 nmol/l excluding 94% of men with classic symptoms of testosterone deficiency.