

## Should women of menopausal and post-menopausal age be supplementing their diet with calcium and vitamin D supplements to support their bone health: A systematic review of randomised controlled trials.

There is no set time in a woman's life for Menopause to start, the average ages of the onset of menopause in the United Kingdom is 51 years (Dunneram, et al, 2013). Symptoms for each woman will be different and will affect them at different stages of the process of change (Santoro, Epperson & Mathews, 2015). Some women will start the perimenopause phase as early as 40 years and the late menopause transition stage (when women experience at least one year of amenorrhea) can be as old as 65 years of age (Dunneram, et al, 2013). The symptoms each woman experiences will be different however they should all be alerted to the development of post-menopausal bone loss and the chance of developing osteoporosis due the reduction of the hormone oestrogen (Weitzmann & Pacifici, 2006). Diet can have a large part to play in the prevention of bone loss, ensuring there is enough calcium and vitamin D in the diet from birth to old age and prevent this silent killer (Jahan,2015).

### Rational.

The average diet of the female of menopausal age does not meet the recommended nutritional intake (RNI) for both calcium and Vitamin D (National diet and Nutrition Survey, 2016). Vitamin D and Calcium are paramount in the prevention of osteoporosis. The World Health Organisation (WHO, 2006) determine a level of bone density  $\geq 2.5$  S.D. below the young female adult mean, to be a deterioration reflective of osteoporosis which effects 22 million women in Europe over the age of 50 years (Hernlund, et al, 2013). The decline in oestrogen with the onset of menopause has a negative effect on the absorption of calcium, leading to a reduction of bone mineral density (BMD) the risk of osteoporosis and fractures (Lerchbaum, 2014).

An adequate source of Vitamin D is required to facilitate the absorption of the calcium (Phillips, 2012). The main physiological role of Vitamin D is to assist in maintaining serum calcium levels enough for the formation of bone (Lean & Combet, 2016). Most of the body's Vitamin D requirement come from the sun with little derived from foods in our diets (Phillips, 2012). In the United Kingdom the sun fails to provide enough vitamin D in the

winter months, so it becomes necessary to supplement, to boost supplies especially for vulnerable groups (Phillips, 2012).

Calcium is required for bone rigidity and is found in many foods in the diet such as dairy foods, green leafy vegetables and fish. The natural sources of calcium such as these are utilised by the body better than supplements (Lean & Combet, 2016). With peak bone mass being achieved by the age of 20-25 years and bone loss beginning from 35-40 years the importance of the correct levels of calcium and Vitamin D being achieved will aid in the prevention of osteoporosis (British Nutrition Foundation, 1991).

If the benefits of using calcium and or vitamin D supplements for menopausal and post-menopausal women can be quantified, and the existing trials prove that the vitamin D and calcium increase bone density, it could improve quality of life and life expectancy for individuals by strengthening of bones to which menopause and age causes deterioration, osteoporosis and prevent fractures in the future (Lerchbaum, 2014). The consequences of this could be a reduction of bone fractures in this population and the subsequent cost of the treatment of these individuals, saving the National Health Service a substantial sum of money (Menopause,2006). In the authors opinion there is a need for continued support physically and mentally for menopausal women as currently there is little support for women of menopausal age, so this could be a valuable document for health professionals to observe and implement. It could be used by Government policy makers to enforce health education messages with the intentions of improving support for women at what can be a difficult time.

### Aims of the study.

The aim of this systematic review is to critically review recent randomised control trials which explore the supplementation of calcium and vitamin D involving menopausal and post-menopausal women. The purpose of this study is to explore what trials have been conducted after 2005 and to understand the results of supplementation and the quantities of the supplementation required. It will explore whether supplementation will prevent the deterioration of bone mineral density and the subsequent development of cases of osteoporosis.

## Methodology

A preliminary search of the library site of University of Wales Trinity St. David (UWTSD), PubMed, Wiley online, Cochrane Library and the American Journal of Medicine have been conducted. Published and unpublished research will be used for this systematic review of Randomised Controlled Trials which will be peer reviewed and be full text articles published between 2006-2018. The reason for the restriction of dates is due to a previous systematic review conducted by W.H.O. in 2006, which identified 38 relevant papers and identified the need for progressive research due to the fast pace of scientific development in this area, so an additional review of this subject is justified using more current data. Articles have not been restricted to English, with the inclusion of articles from other countries and subjects of other nationalities.

Keywords and combinations of keywords for the searches where: *-Menopause, Post-menopause, Vitamin D, Calcium, Randomised controlled trials.*

Initial screening of the papers included the reading of the abstract to evaluate the contents in accordance with the keywords, identifying associating evidence.

The inclusion criteria for the study is females at differing stages of menopause, peri and post-menopausal stages, studies which include the observations of Vitamin D<sub>2</sub> and D<sub>3</sub> with and without the intervention of Calcium. The ages of the participants within the various studies to be included varies due to the nature of menopause but all identify as being between 40-70 years of age.

The exclusions criteria for the study where, when further interventions such as Hormone Replacement Therapy (HRT) or exercise had been considered as these can affect bone modelling. Those articles including data on those who have further underlying conditions such as thyroid disease have been excluded as treatments to control thyroid function affect the absorption of vitamin D and or Calcium (Mackawy, Al-Ayed, & Al-Rashidi, 2013).

Randomised controlled trials (RCT) were selected as the most rigorous way of scrutinising the possibility of a connection between the supplementation and bone density at this stage of life with the least chance of bias with the least confounding influence. They determine whether there is a cause-effect relation existing between treatment and outcome therefore identifying if it is a viable or cost effective to implement (British Medical Journal (BMJ))

,1998). To be an RCT the subjects are randomly allocated to the intervention or control groups, but both are treated the same way except for the experimental treatment, some of the trials will be described as double-blinded where the subjects and the trialist are unaware of who has which intervention (BMJ, 1998). No ethical approval was required for this systematic review as only RCT data will be used.

The time of year the trials were conducted will be taken into consideration to observe the ultra violet (UV) output of sun and the location in the world so including information from countries with high UV output.

All journals will be analysed with the assistance of The Critical Appraisal Skills Program (CASP) (2013) to ensure they meet the inclusion criteria

### Time table of work

October. Choose a topic of interest. Formulate title question. Gather relevant resources for the literature review. Complete proposal for presentation and submission.

November. Continue to gather literature. Prepare summary table of literature collected forming the correct criteria relevant to the systematic review. Source any further literature required direct from writer or via the Academic Liaison within the library.

December. Write introduction literature review to be assessed by supervisor prior to Christmas.

January. With the aid of the prepared summary table write results.

February. Write discussion

March. Complete conclusion. Present to supervisor for assessment and editing. Complete re-write.

April. Prior to end of supervision have final discussion / editing

Submit 2 copies of complete dissertation

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