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Randomized Control Trial
Dietary Supplementation with Prunes on Bone Density, Geometry & Estimated Bone Strength in Postmenopausal Women

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Benefits to the Industry

- Further regulatory support for benefits to bone health in postmenopausal women with low bone mass – EFSA
- Non-pharmaceutical strategy for women to improve bone health
- Potential to provide information on both research priorities: bone and gut health
- Reasons to purchase prunes

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Research Team

- Principal Investigator
  - Mary Jane De Souza PhD,
    Professor, Kinesiology and Physiology
- Co-Investigators
  - Nancy Williams, ScD,
    Professor of Kinesiology & Physiology,
    Head, Department of Kinesiology
  - Connie Weaver PhD,
    Distinguished Professor & Department Head, Nutrition Science,
    Purdue University, Indiana
  - Mario Feruzzi PhD,
    Professor, Translational Nutrition, Department of Food,
    Bioprocessing & Nutrition Science, North Carolina State University

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Snapshot of the Study

- One year clinical trial
- Postmenopausal women 55-75
- Low bone mineral density
- 300 women screened to have 63 completers per group
  - Control Group: no prunes + Ca & $VitD_3$
  - 50 g Prune Group: (5-7 prunes/day) + Ca & $VitD_3$
  - 100 g Prune Group: (10-12 prunes/day) + Ca & $VitD_3$

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Aims to Explore

- Compared to control group, prunes'
  - effect on **bone mineral density** (BMD)
  - effect on **bone geometry** and **estimated bone strength** (3-dimensional bone imaging technology)
- **Phenolics** and metabolites related to bone outcomes (measured in urine)
- Effect on markers of bone **resorption and formation** (mechanisms analysis)
- Effects on **inflammatory markers** and cytokines
- Effect on **gut microbiome** related to bone outcomes (full fecal sampling – analysis TBD)

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Research Budget

	2016	2017	2018	Total
Research Costs	**$387,000**	**$263,000**	**$199,000**	**$849,000**
Funded by:				
CA Prune Board	**$459,000**			
Int'l Prune Assoc.	**$390,000**			

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Study Design

300 postmenopausal women aged 55-75 with low bone density randomized to one of three groups:

- Control Group: No Prunes + Ca & $VitD_3$ N=63
- 50 g Prune Group: (5-7 prunes/day) + Ca & $VitD_3$ N=63
- 100 g Prune Group: (10-12 prunes/day) + Ca & $VitD_3$ N=63

Primary Outcomes:

1) Bone density
2) Bone geometry
3) Estimated bone strength
4) Bone markers

Secondary Outcomes:

1) Inflammatory Markers
2) Secondary bone markers
3) Microbiota

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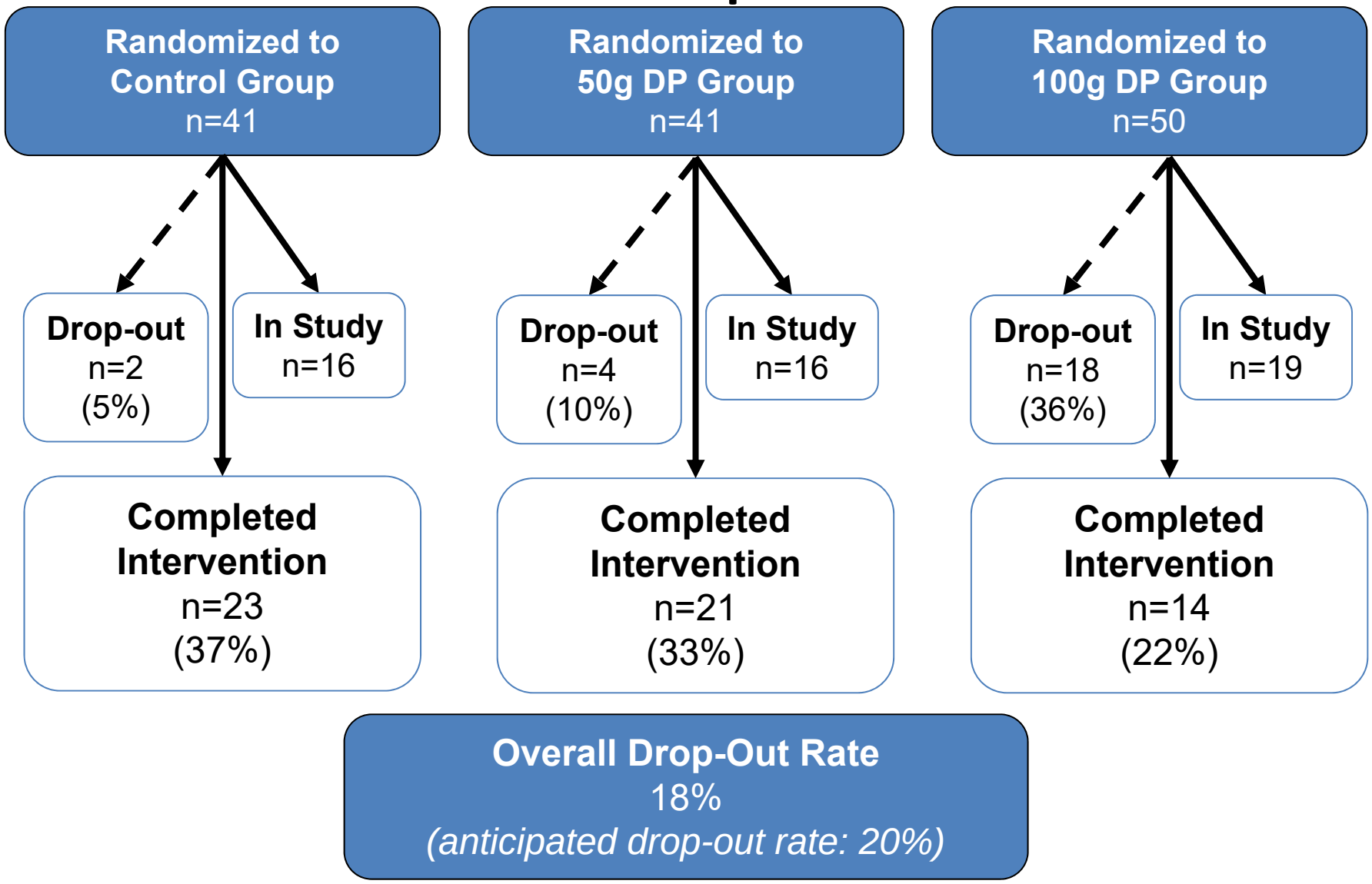
Study Drop-Out and Completion Rates



Flyer Advertisements

Newspaper Articles

THE CENTRE COUNTY GAZETTE

Post-menopausal osteoporosis: Is medication your only option?

By EMILY SOUTHMAYD
Special to the Gazette

UNIVERSITY PARK — Estrogen, one of the chief reproductive hormones in women, is a powerful signal affecting many systems in the body. One important function of estrogen is to prevent bone breakdown, and when estrogen levels decline sharply in women going through menopause, excess bone breakdown can lead women down the path to osteoporosis and increase the risk for fractures, particularly in the wrist, hip, pelvis and spine. Fractures, in turn, can greatly diminish mobility and quality of life.

While pharmaceutical agents, such as hormone therapy and bisphosphonate drugs, are commonly prescribed to combat post-menopausal bone loss, these come with a host of other side effects and are not suitable for everyone. Luckily, there may be other options, including some you can find right in your own grocery store. The Women's Health and Exercise Laboratory at Penn State is conducting a study to examine the impact of one such alternative: dried plums (i.e. prunes).

Dr. Mary Jane De Souza, the principal investigator of the Dried Plum and Bone Health Study, is a professor of kinesiology and physiology at Penn State and has a prolific research history in reproductive endocrinology and bone health in women. De Souza has worked closely with the California Dried Plum Board, the association sponsoring the study, to design the one-year clinical trial that is testing the effect of eating six to 12 dried plums per day on bone mineral density, which is the clinical criterion used to diagnose osteoporosis.

Penn State photo

THE WOMEN'S HEALTH and Exercise Laboratory at Penn State is conducting a study of dried plums to see if the agents in the food can combat post-menopausal bone loss.

The Dried Plum and Bone Health Study was developed after previous research in rodents and two smaller trials in humans reported benefits for bone health with dietary dried plum consumption. Dried plums are likely impacting bone health through a variety of overlapping mechanisms.

"Dried plums contain molecules called 'phenolic compounds' that may mitigate damaging reactive oxygen species and prevent oxidative stress from harming bone," said De Souza. "These compounds may relieve inflammation that occurs with menopausal estrogen loss and affects bone.

"We also predict that the dried plums will alter the gut microbiome, the colonies of helpful and harmful bacteria that live in the gut and impact digestion, immune function and, as we understand it, bone health."

The study aims to evaluate all of these potential mechanisms.

"Osteoporosis is known as a silent disease because so many women have low bone density without knowing it until a fracture occurs, and then it is too late," said De Souza. "Our goal is to educate women about their bone health and to offer an alternative to medication to prevent bone loss that can result in debilitating fractures."

The Women's Health and Exercise Laboratory will continue recruiting participants for the study for the next two years. Eligibility criteria include: age 55 to 75, at least one year post-menopausal, generally healthy, non-smoking, not currently taking osteoporosis medication and willing to add dried plums to one's daily diet.

Women interested in participating can call (814) 863-4488 or email driedplums@psu.edu.

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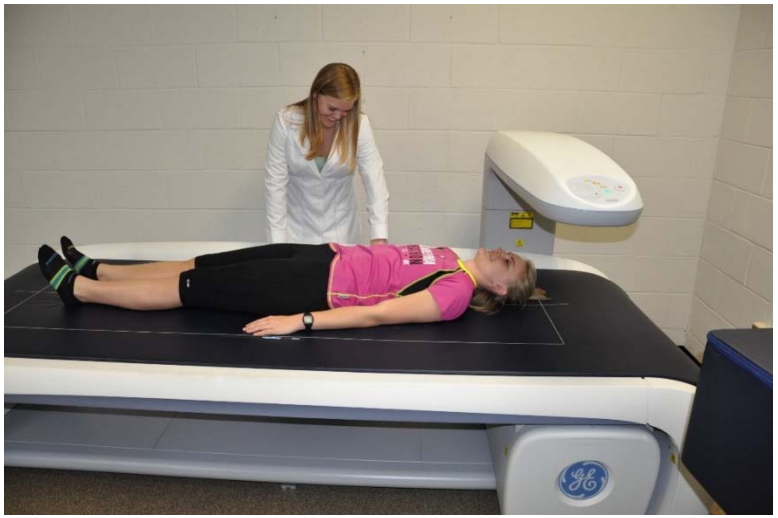
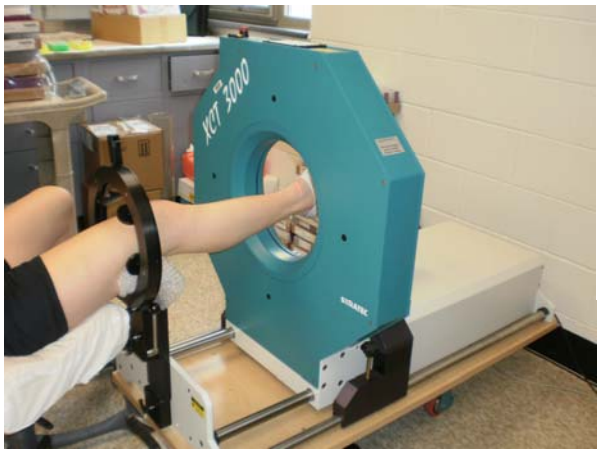
Bone Density, Geometry, and Strength



Dual-Energy X-ray Absorptiometry (DXA)



Peripheral Quantitative Computed Tomography (pQCT)

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Phenolic Compounds

- **Phenolic Compounds** are a class of *phytochemicals* (plant-derived molecules) found in dried plums and other plant foods
- **Phenolic Compounds** have *antioxidant* properties that could help reduce reactive oxygen species (ROS)
  - Reactive oxygen species (ROS) are an indicator of "oxidative stress"
  - Oxidative stress is associated with bone breakdown
  - Less oxidative stress = less bone breakdown

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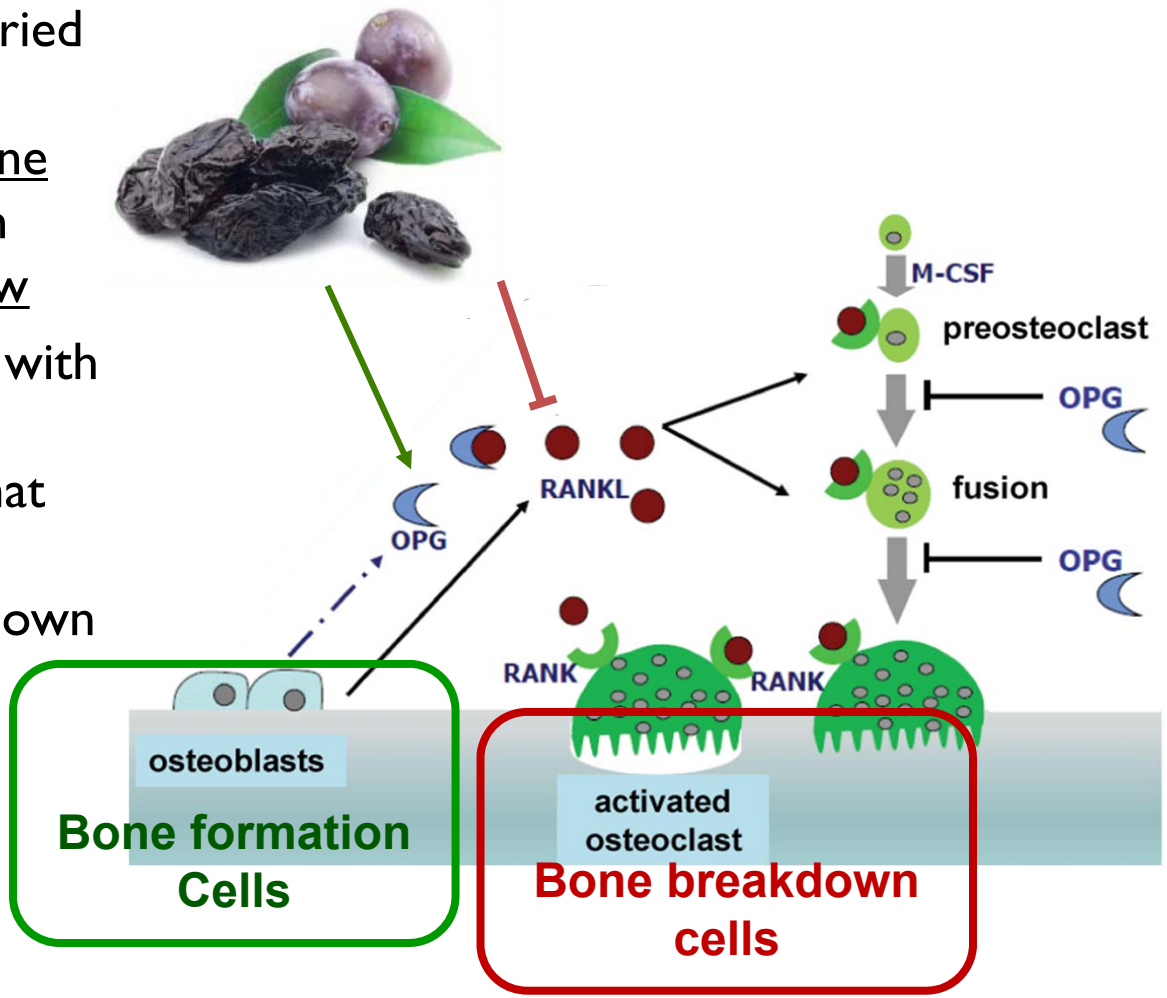
Bone Turnover Mechanisms

- Previous studies have demonstrated effects of dried plum consumption on *increases* in markers of bone formation and *decreases* in markers of bone breakdow
- Dried plums may interact with signaling molecules in the bone turnover pathway that result in greater bone formation and less breakdown



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Inflammatory Markers

- "Inflammation" is a term used to describe an immune response that can be localized to a specific tissue or widespread throughout the body
  - Inflammation can be acute (in response to a specific event) or chronic (as a result of long-term health issues or other factors)
- Animal studies have demonstrated that the phenolic compounds in dried plums may interrupt inflammatory molecules that have downstream effects on bone
  - Decreasing inflammation → decreased bone breakdown

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Gut Microbiome

- The gut microbiome is the complete genetic makeup of the microbiota (organisms) that live in our digestive tract
- Changes in the microbiome can have downstream effects on health
- We hypothesize that eating dried plums (and the fiber associated with them) may alter the gut microbiome and have benefits for bone health