Reducing High Risk Medications to Prevent Falls and Injuries in Older Adults

Funded by the Centers for Disease Control and Prevention U01CE002967

Study Goal

Objective

Test a deprescribing intervention to reduce use of high-risk medications and fall-related injuries

Key features

- Evidence-based strategies (adapted from D-PRESCRIBE trial*)
- Health-system-embedded
- Non-pharmacologic alternatives
- Patient-centered

*Martin P, et al. *JAMA*. 2018;320(18):1889-1898.

Specific Aims

Aim 1. *ADAPT AND PILOT-TEST* an evidence-based medication reduction strategy for use in an integrated health care system

Aim 2. *IMPLEMENT AND EVALUATE* the adapted intervention using a cluster randomized controlled trial design

Aim 3. *ASSESS* barriers and facilitators to intervention implementation

Project Team

Kaiser Permanente Washington:

- Benjamin Balderson Psychologist, Site PI
- Cara Lewis Implementation Scientist
- Andrea Cook Biostatistician
- Brian Williamson Biostatistician
- Monica Fujii Research Coordinator
- Kanichi Nakata Research Scientist
- Kay Theis Programmer
- Vina Graham Programmer

Consultants:

- Cara Tannenbaum, MD
- Justin Turner, PhD

Target Medications*

Sedative-hypnotics (benzodiazepines, Z-drugs)

Opioids

Skeletal muscle relaxants

Tricyclic antidepressants

First-generation antihistamines

*Medications classified as high-risk for falls by the CDC and considered potentially inappropriate medications according to the Beers Criteria.

Study Design

Pragmatic, cluster-randomized controlled trial

18 KPWA clinics (9 intervention, 9 control)

Patients followed up to 24 months for outcomes

Eligibility Criteria

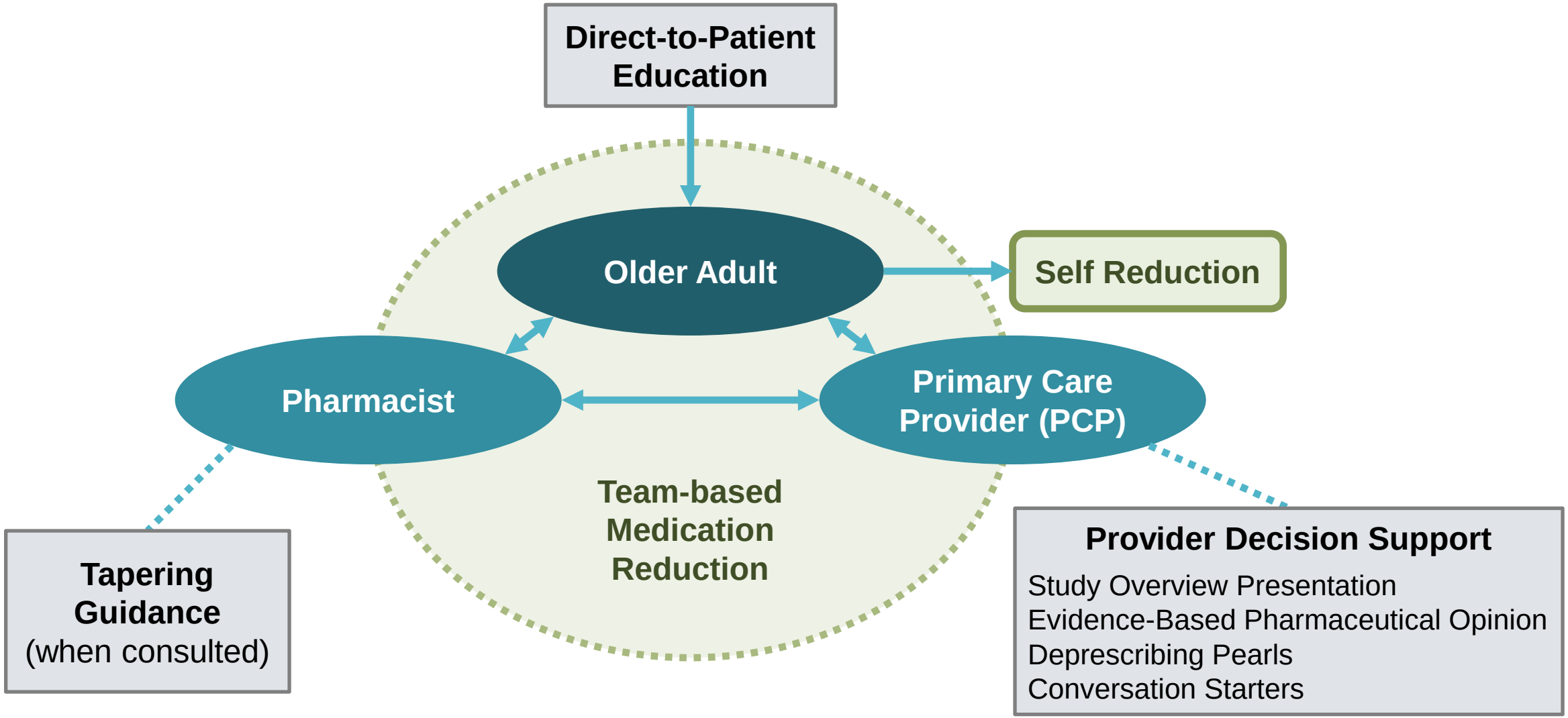
Inclusion criteria

- Aged ≥60 years receiving primary care at KPWA clinic
- Taking at least 1 target medication for ≥3 months

Exclusion criteria

- Dementia
- Residing in a skilled nursing facility
- Recent cancer treatment
- Palliative care or hospice

STOP-FALLS: Intervention



Materials sent prior to a scheduled visit (virtual or in-person)*: Primed for a deprescribing discussion

Mail medication brochure and self-care handouts to patient

Staff Message to PCP with URL to EBPO

Patient Visit

*Or at other points during study if no visit scheduled

8-40 days

Patient Brochure Example & Self-Care Handouts

Patient Brochures

Major Sections

Test your knowledge

Did you know

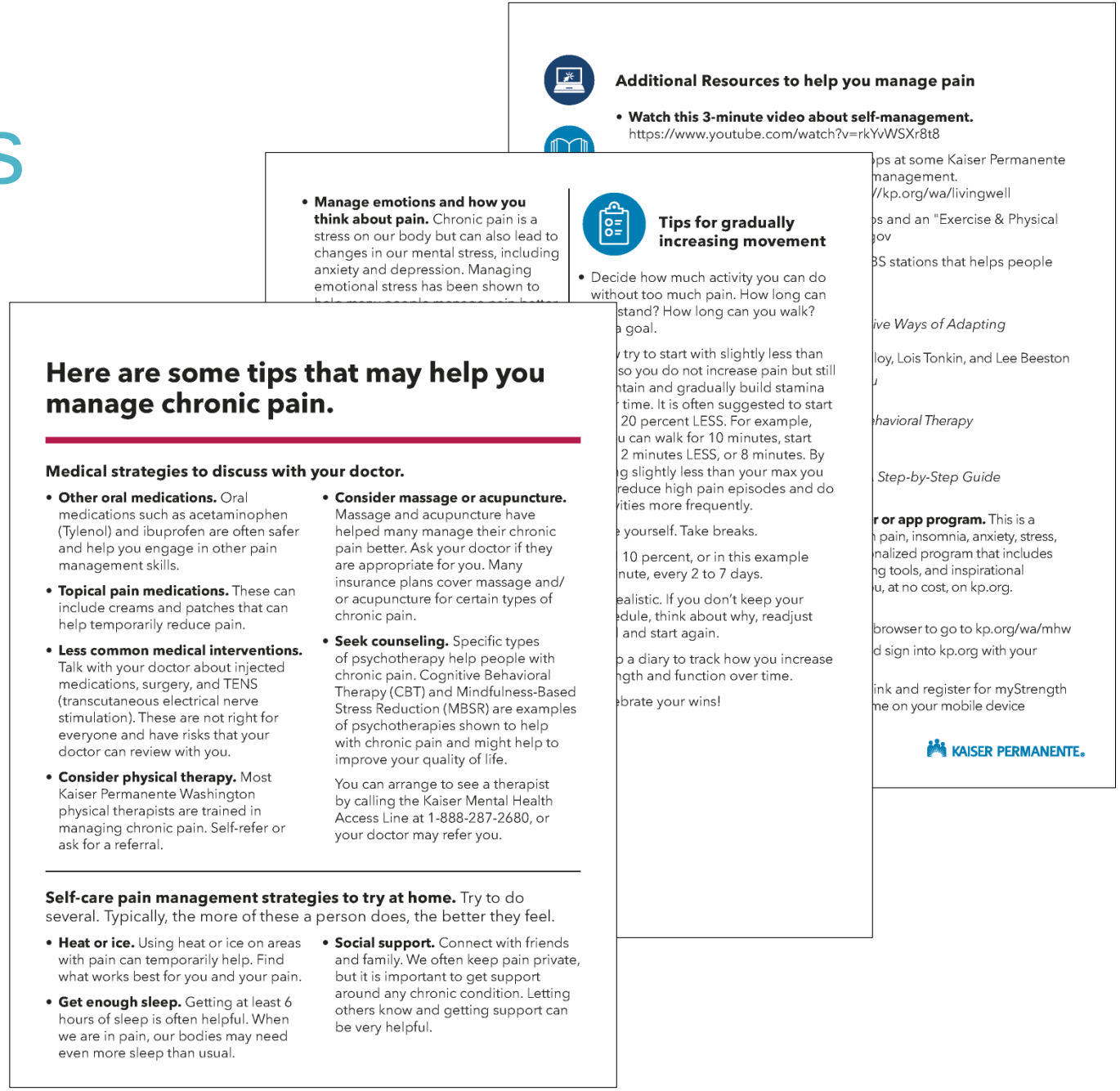
So ask yourself

Patient testimonial

Preparing to speak to the doctor

Self-Care Handouts

- Mailed to patient with medication brochure
- Cover evidence-based strategies for symptom management
  - Allergies
  - Anxiety
  - Insomnia
  - Pain
- Emphasize KPWA resources



Additional Resources to help you manage pain

- **Watch this 3-minute video about self-management.** https://www.youtube.com/watch?v=rkYvWSXr8t8

ps at some Kaiser Permanente
management.
//kp.org/wa/livingwell

s and an "Exercise & Physical
ov

S stations that helps people

ive Ways of Adapting

loy, Lois Tonkin, and Lee Beeston

havioral Therapy

Step-by-Step Guide

r or app program. This is a
pain, insomnia, anxiety, stress,
nalized program that includes
g tools, and inspirational
u, at no cost, on kp.org.

browser to go to kp.org/wa/mhw
d sign into kp.org with your

ink and register for myStrength
me on your mobile device

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- **Manage emotions and how you think about pain.** Chronic pain is a stress on our body but can also lead to changes in our mental stress, including anxiety and depression. Managing emotional stress has been shown to

Tips for gradually increasing movement

- Decide how much activity you can do without too much pain. How long can stand? How long can you walk? goal.

try to start with slightly less than so you do not increase pain but still ntain and gradually build stamina time. It is often suggested to start 20 percent LESS. For example, u can walk for 10 minutes, start 2 minutes LESS, or 8 minutes. By g slightly less than your max you reduce high pain episodes and do vities more frequently.

yourself. Take breaks.

10 percent, or in this example nute, every 2 to 7 days.

ealistic. If you don't keep your edule, think about why, readjust and start again.

a diary to track how you increase ngth and function over time.

ebrate your wins!

Here are some tips that may help you manage chronic pain.

Medical strategies to discuss with your doctor.

- **Other oral medications.** Oral medications such as acetaminophen (Tylenol) and ibuprofen are often safer and help you engage in other pain management skills.
- **Topical pain medications.** These can include creams and patches that can help temporarily reduce pain.
- **Less common medical interventions.** Talk with your doctor about injected medications, surgery, and TENS (transcutaneous electrical nerve stimulation). These are not right for everyone and have risks that your doctor can review with you.
- **Consider physical therapy.** Most Kaiser Permanente Washington physical therapists are trained in managing chronic pain. Self-refer or ask for a referral.
- **Consider massage or acupuncture.** Massage and acupuncture have helped many manage their chronic pain better. Ask your doctor if they are appropriate for you. Many insurance plans cover massage and/or acupuncture for certain types of chronic pain.
- **Seek counseling.** Specific types of psychotherapy help people with chronic pain. Cognitive Behavioral Therapy (CBT) and Mindfulness-Based Stress Reduction (MBSR) are examples of psychotherapies shown to help with chronic pain and might help to improve your quality of life.

  You can arrange to see a therapist by calling the Kaiser Mental Health Access Line at 1-888-287-2680, or your doctor may refer you.

Self-care pain management strategies to try at home. Try to do several. Typically, the more of these a person does, the better they feel.

- **Heat or ice.** Using heat or ice on areas with pain can temporarily help. Find what works best for you and your pain.
- **Get enough sleep.** Getting at least 6 hours of sleep is often helpful. When we are in pain, our bodies may need even more sleep than usual.
- **Social support.** Connect with friends and family. We often keep pain private, but it is important to get support around any chronic condition. Letting others know and getting support can be very helpful.

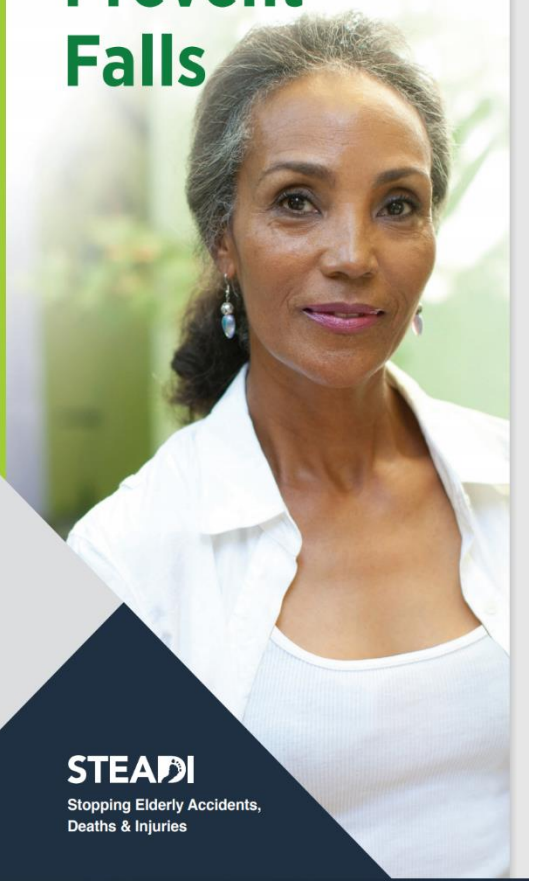
Many falls can be prevented.

By making some changes, you can lower your chances of falling.

Four things YOU can do to prevent falls:

- Have your healthcare provider review your medicines.
- Exercise to improve your balance and strength.
- Have your eyes and feet checked.
- Make your home safer.

What YOU Can Do to Prevent Falls



For more information, contact Centers for Disease Control and Prevention 1-(800)-CDC-INFO (232-4636) or visit www.cdc.gov/steadi

For information about fall prevention, visit go.usa.gov/xN9XA

For more information about hypotension, visit
www.mayoclinic.com
www.webmd.com

Centers for Disease Control and Prevention
National Center for Injury Prevention and Control

2017

STEADI
Stopping Elderly Accidents, Deaths & Injuries

Fall Prevention Tips

Evidence-Based Pharmaceutical Opinion (EBPO) Example

Evidence-based Pharmaceutical Opinion: Sedative-Hypnotics (Benzodiazepines and Z-drugs)

The 2019 American Geriatrics Society Beers List[1] of drugs to avoid in older adults considers benzodiazepines and Z-drugs as potentially inappropriate medications for adults aged 65+ due to an increased risk of cognitive impairment, falls, fractures, and motor vehicle crashes, even with intermittent use.

[1] American Geriatrics Society 2019 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults. American Geriatrics Society Beers Criteria® Update Expert Panel. *J Am Geriatr Soc* 2019;67:674-694.

Suggested Strategies

☐ **Taper Medication**

- **Route to pharmacy pool for consult {.HRMCONSULT}** to obtain a tapering schedule. You as the provider will need to initiate the taper and work with the patient.
- **Implement and follow the benzodiazepine tapering schedule as per KPWA guidelines** (see last page for pictorial representation for patients).
- **Implement the Z-drug tapering schedule as per KPWA guidelines:** Decrease the number of days per week that the patient takes the medication (e.g., 6 nights per week x2 weeks, then 5 nights per week x2 weeks, etc).

☐ **Psychotherapy**. For psychotherapy for anxiety or insomnia, **refer to a Licensed Clinical Social Worker (LICSW) in your clinic** if available **or to KPWA Mental Health and Wellness** Services. The patient may also be referred to the **myStrength self-care app**, free to all KPWA members, for help with anxiety or insomnia. Use the **AVS smart phrase .mystrengthinformation**.

☐ **For insomnia**, recommend a **Cognitive Behavioral Therapy workbook**; several are listed in the **After Visit Summary material .avsinsomniaptinfo**.

Symptom Monitoring During Tapering

Brief, validated tools are available in Epic (flowsheets) for tracking changes in symptoms over time and can facilitate medication tapering/dose reduction. In addition to monitoring symptoms of the condition for which this medication was prescribed, consider also monitoring related symptoms. Available tools include:

- PEG Pain Screening Tool (PEG)
- Generalized Anxiety Disorder 7-item scale (GAD-7)
- Patient Health Questionnaire-9 (PHQ-9)
- Insomnia Severity Index (ISI)

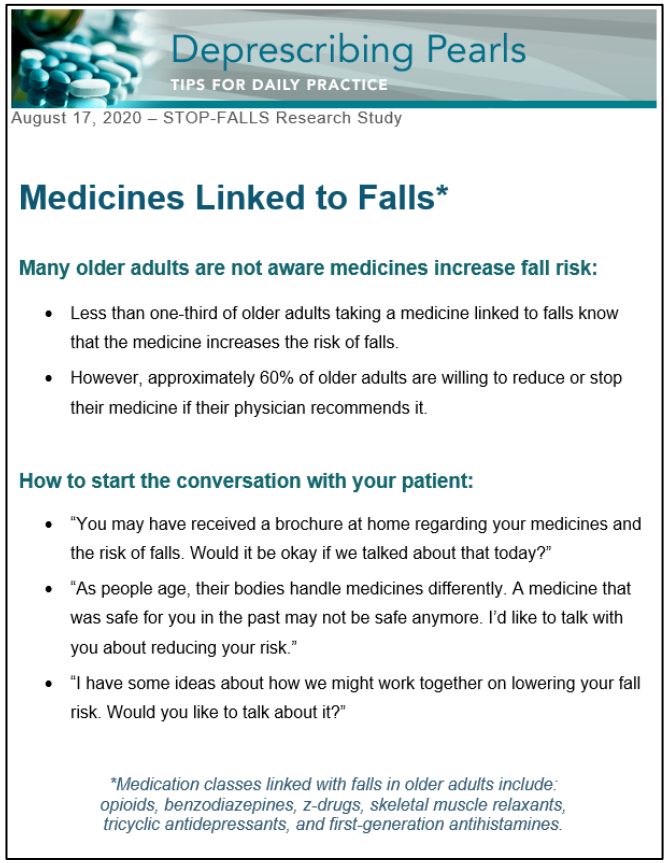
Alternatives for Anxiety	
• Selective serotonin reuptake inhibitor (SSRI) (e.g., sertraline, escitalopram)* • Selective serotonin norepinephrine reuptake inhibitor (SNRI) (e.g., duloxetine)* • Buspirone	*These medications are preferred over sedative-hypnotics because of a more favorable side effect profile. However, they may still increase fall risk. **After Visit Summary** .avsanxiety

Alternatives for Insomnia
• Melatonin • Ramelteon
After Visit Summary .avsinsomniaptinfo

EPBO Example

- Rationale for deprescribing
- Evidence about drug harms
- Suggested strategies
  - Non-pharmacologic alternatives
  - Symptom monitoring

Deprescribing Pearls & Conversation Starters



Deprescribing Pearls

TIPS FOR DAILY PRACTICE

August 17, 2020 – STOP-FALLS Research Study

Medicines Linked to Falls*

Many older adults are not aware medicines increase fall risk:

- Less than one-third of older adults taking a medicine linked to falls know that the medicine increases the risk of falls.
- However, approximately 60% of older adults are willing to reduce or stop their medicine if their physician recommends it.

How to start the conversation with your patient:

- "You may have received a brochure at home regarding your medicines and the risk of falls. Would it be okay if we talked about that today?"
- "As people age, their bodies handle medicines differently. A medicine that was safe for you in the past may not be safe anymore. I'd like to talk with you about reducing your risk."
- "I have some ideas about how we might work together on lowering your fall risk. Would you like to talk about it?"

**Medication classes linked with falls in older adults include: opioids, benzodiazepines, z-drugs, skeletal muscle relaxants, tricyclic antidepressants, and first-generation antihistamines.*

Resources:

- For more information about tips and evidence-based tools for deprescribing, click here for short (3 minute) videos.
- For a printable PDF pocket guide to the 2019 American Geriatrics Society Beers Criteria, click here.
- Links to KPWA clinical guidelines for:
  - Chronic Opioid Therapy (COT) Safety for Patients on COT for Chronic Non-malignant Pain here.
  - Benzodiazepine and Z-Drug Safety here.
  - Insomnia here.

STOP-FALLS Research Study

Email: Monica.M.Fujii@kp.org
Phone: 1-888-324-3166

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13 Deprescribing Pearls:

- Medicines Linked To Falls
- Sedative-Hypnotics
- Opioids
- OTC Antihistamines
- Skeletal Muscle Relaxants
- Tricyclic Antidepressants
- Use of Multiple Drugs Acting on the CNS
- Withdrawal Symptom Management
- Prescribing Inertia
- Use Patient Clues for Opioid De-Rx
- Patient-Provider Relationship
- Return of Underlying Medical Condition
- Deprescribing Triggers

Outcome Measures

Outcomes	Parameter of Interest	Primary Time Point for Analysis	Data Source
Primary			
First medically treated fall*	Hazard rate	N/A (time to event)	Utilization database
Secondary (Medication)			
Discontinuation**	Relative risk	6 months	Computerized pharmacy data
Sustained discontinuation**	Relative risk	6 months	Computerized pharmacy data
Dose reduction**	Relative risk	6 months	Computerized pharmacy data
Safety			
Serious adverse drug withdrawal events (urgent, ED visits and hospitalizations)	Proportion	6 months	Utilization database
Unintentional overdose	Proportion	6 months	Utilization database
Deaths	Proportion	End of follow-up	Utilization database

* Competing risk of primary outcome = time to non-fall death; composite outcome = time to first medically treated fall or non-fall death
**At least one target medication and by medication class

Statistical Analysis

Primary outcome: time-to-event analysis accounting for competing risks and cluster randomization

- Cause-specific proportional hazards regression to estimate adjusted cause-specific hazard ratios
- Adjusted cause-specific cumulative incidence curve for first incident medically treated fall and death
- Heterogeneity of intervention effect in pre-specified subgroups (age, sex, h/o prior fall, multimorbidity, frailty)

Secondary (medication) outcomes: Poisson regression using GEE, adjusting for baseline dose of target medication

Results

- Participant Characteristics
- Primary Outcome
- Medication Outcomes
- Safety Outcomes

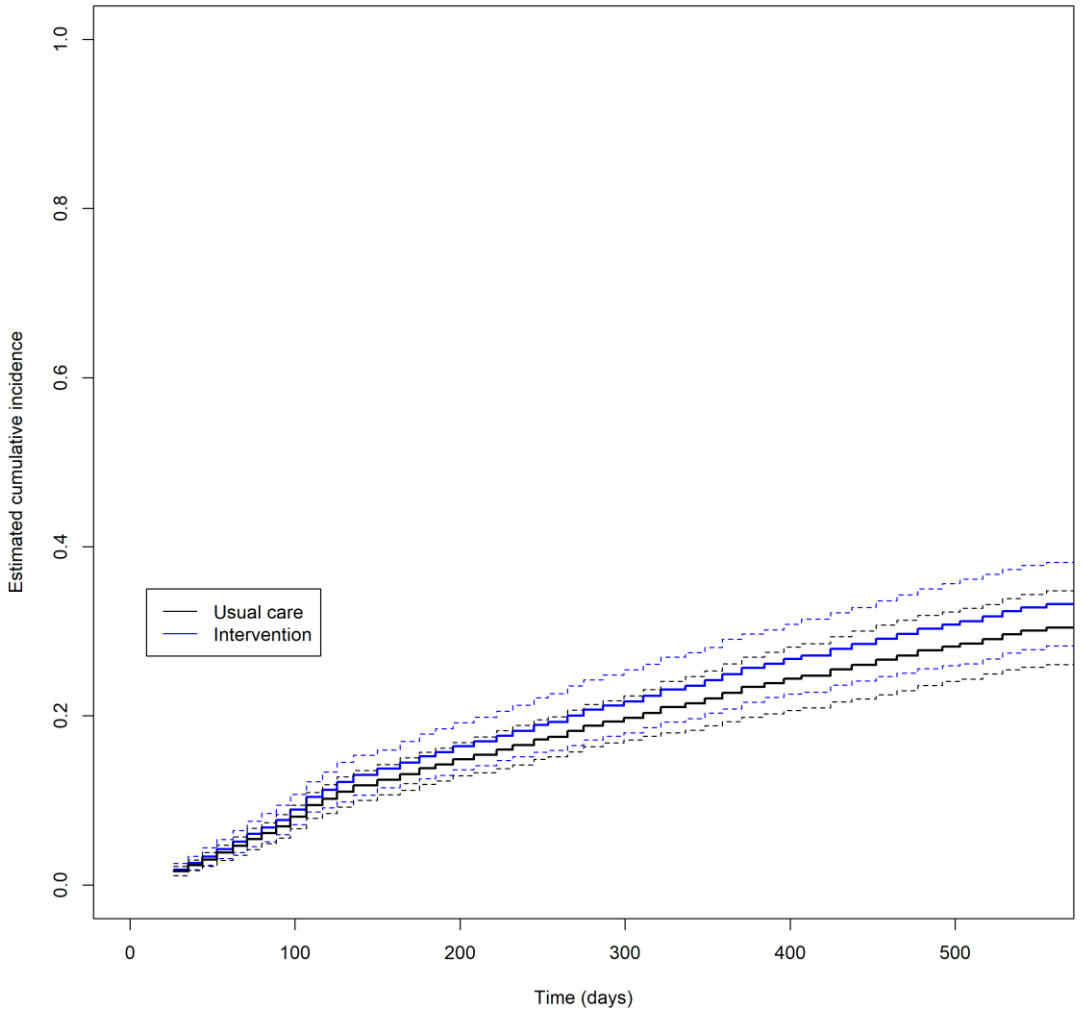
Participant Demographics and Health Characteristics

	Intervention (N=1106)	Control (N=1261)
Age, mean (SD)	70 (7.4)	71 (7.7)
Female, %	64	62
Non-white, %	13	13
Chronic conditions, mean (SD)	2 (1.5)	2 (1.6)
Non-frail, %	45	45
Medical care for a fall in prior year, %	29	30
Number of target medications prescribed, %		
One	90	89
Two or more	10	11

Participant Demographics and Health Characteristics (cont'd)

	Intervention (N=1106)	Control (N=1261)
Target Medication Class Prescribed, %		
Opioid	69	69
Benzodiazepine	14	14
Z-drug	8	8
Skeletal muscle relaxant	8	8
Tricyclic antidepressant	11	11
Antihistamine	2	2

Time to First Medically Treated Fall



aHR = 1.11 (95% CI, 0.94-1.31)

Heterogeneity of Treatment Effect

	Cause-specific outcome analysis: time to first medically-treated fall		Cause-specific outcome analysis: time to non-fall death	
Variable	**Ratio of HRs (95% CI)**	**p-value from LRT**	**Ratio of HRs (95% CI)**	**p-value from LRT**
Age (< 80 vs 80+)	0.996 (0.732, 1.356)	0.98	0.737 (0.226, 2.405)	0.59
Sex assigned at birth	0.964 (0.727, 1.278)	0.79	1.903 (0.767, 4.725)	0.21
Any fall prior to baseline	1.008 (0.778, 1.305)	0.95	1.014 (0.331, 3.109)	0.98
Multimorbidity	1.016 (0.855, 1.207)	0.91	0.87 (0.114, 6.642)	0.83
Frailty	1.107 (0.826, 1.484)	0.71	--†	--
Definitions: "HR" = hazard ratio; "LRT" = likelihood ratio test.				
All analyses used a cause-specific Cox proportional hazards model for a given outcome censoring for disenrollment, study follow-up end, or for the competing risk outcome if applicable (e.g. for time to medically treated fall the analysis would censor for death). All models adjusted for geographic region of the clinic, age, sex assigned at birth, and any falls prior to baseline.				

†The regression model with an interaction between frailty and intervention arm failed to converge, because no deaths were observed among those with frailty in the usual care arm and only one death was observed among those with frailty in the intervention arm.

Medication Outcomes: 6 Months

		Usual Care (N=1261)	Intervention (N=1106)	
	N	Adj Rate (95 % CI)	Adj Rate (95 % CI)	Adj RR (95% CI)
Discontinuation*				
Opioid	1588	0.04 (0.03, 0.06)	0.04 (0.03, 0.06)	0.88 (0.54, 1.45)
Benzodiazepine/Z-drug	465	0.20 (0.17, 0.25)	0.20 (0.17, 0.25)	0.99 (0.78, 1.26)
Tricyclic Antidepressant	273	0.13 (0.09, 0.17)	0.23 (0.18, 0.28)	1.79 (1.29, 2.50)
Muscle Relaxant	184	0.39 (0.33, 0.47)	0.39 (0.27, 0.57)	0.99 (0.65, 1.51)
Antihistamines (Rx)**	55			
First Target Med	2288	0.09 (0.08, 0.11)	0.12 (0.09, 0.15)	1.24 (0.90, 1.70)
	N	Adj Mean (95 % CI)	Adj Mean (95 % CI)	Adj Diff (95% CI)
Dose Reduction				
Opioid	1588	-0.28 (-0.36, -0.20)	-0.29 (-0.38, -0.21)	-0.01 (-0.13, 0.11)
Benzodiazepine/Z-drug	465	-0.91 (-1.13, -0.69)	-0.84 (-1.00, -0.68)	0.07 (-0.22, 0.36)
Tricyclic Antidepressant	273	-0.72 (-1.15, -0.29)	-1.57 (-1.94, -1.20)	-0.85 (-1.35, -0.34)
Muscle Relaxant	184	-2.73 (-3.14, -2.31)	-2.66 (-3.3, -2.03)	0.06 (-0.72, 0.85)
Antihistamines (Rx)	55	-0.10 (-0.19, -0.01)	-0.13 (-0.27, 0.01)	-0.03 (-0.19, 0.13)
First Target Med	2288	-0.47 (-0.61, -0.32)	-0.61 (-0.68, -0.54)	-0.14 (-0.29, 0.01)

* 90 days SDD=0 post 6 months; **model did not converge

Medication Outcomes: 9-15 Months

	N	9 months Adj RR (95% CI)	12 months Adj RR (95% CI)	18 months Adj RR (95% CI)
Discontinuation				
Opioid	1588	0.89 (0.63, 1.25)	1.01 (0.66, 1.55)	1.06 (0.79, 1.41)
Benzodiazepine/Z-drug	465	1.20 (1.01, 1.42)	1.02 (0.88, 1.17)	0.95 (0.79, 1.14)
Tricyclic Antidepressant	273	1.95 (1.36, 2.8)	1.93 (1.39, 2.68)	1.61 (1.25, 2.08)
Muscle Relaxant	184	0.98 (0.68, 1.43)	0.95 (0.67, 1.33)	1.10 (0.75, 1.62)
Antihistamines (Rx)	55	9.60 (1.17, 79.09)	3.24 (1.18, 8.86)	2.34 (0.85, 6.49)
First Target Med	2288	1.27 (1.00, 1.62)	1.19 (0.96, 1.48)	1.12 (0.93, 1.35)
		Adj Diff (95% CI)	Adj Diff (95% CI)	Adj Diff (95% CI)
Dose Reduction				
Opioid	1588	-0.03 (-0.20, 0.13)	-0.03 (-0.20, 0.13)	-0.06 (-0.26, 0.15)
Benzodiazepine/Z-drug	465	-0.01 (-0.30, 0.29)	-0.01 (-0.30, 0.29)	0.23 (-0.14, 0.61)
Tricyclic Antidepressant	273	-0.74 (-1.40, -0.08)	-0.74 (-1.40, -0.08)	-1.03 (-1.71, -0.36)
Muscle Relaxant	184	-0.06 (-0.67, 0.56)	-0.06 (-0.67, 0.56)	-0.22 (-0.94, 0.49)
Antihistamines (Rx)	55	-0.04 (-0.30, 0.21)	-0.04 (-0.30, 0.21)	-0.08 (-0.36, 0.20)
First Target Med	2288	-0.14 (-0.33, 0.05)	-0.14 (-0.33, 0.05)	-0.09 (-0.26, 0.09)

Safety Outcomes

	Intervention (N=1106)	Usual Care (N=1261)
Death, n (%)	72 (6.9)	86 (6.8)
ADWE, n (%)*	10 (1.1)	4 (0.4)
Unintentional overdose, n (%)	6 (0.5)	5 (0.4)

*ADWE = serious adverse drug withdrawal events among those chronically prescribed a benzodiazepine or opioid. Sample size for analysis: intervention=914; usual care=1032.

Strengths

- Complete capture of healthcare utilization
- Long duration of follow-up for primary outcome ascertainment
- Sufficient power to detect an effect on medically treated falls

Limitations

- Few non-white and frail participants
- No information about deprescribing discussions
- Effect on some outcomes (e.g., non-prescription antihistamine use; non-medically treated falls) unknown

Conclusions

- The STOP-FALLS intervention did not reduce medically treated falls
- The intervention was no more effective than usual care in reducing use of most classes of the CNS-active medications targeted in the trial

Discussion and Questions

Phelan, Elizabeth. Peer Teaching Evaluation. 05.14.2024


THANK YOU!

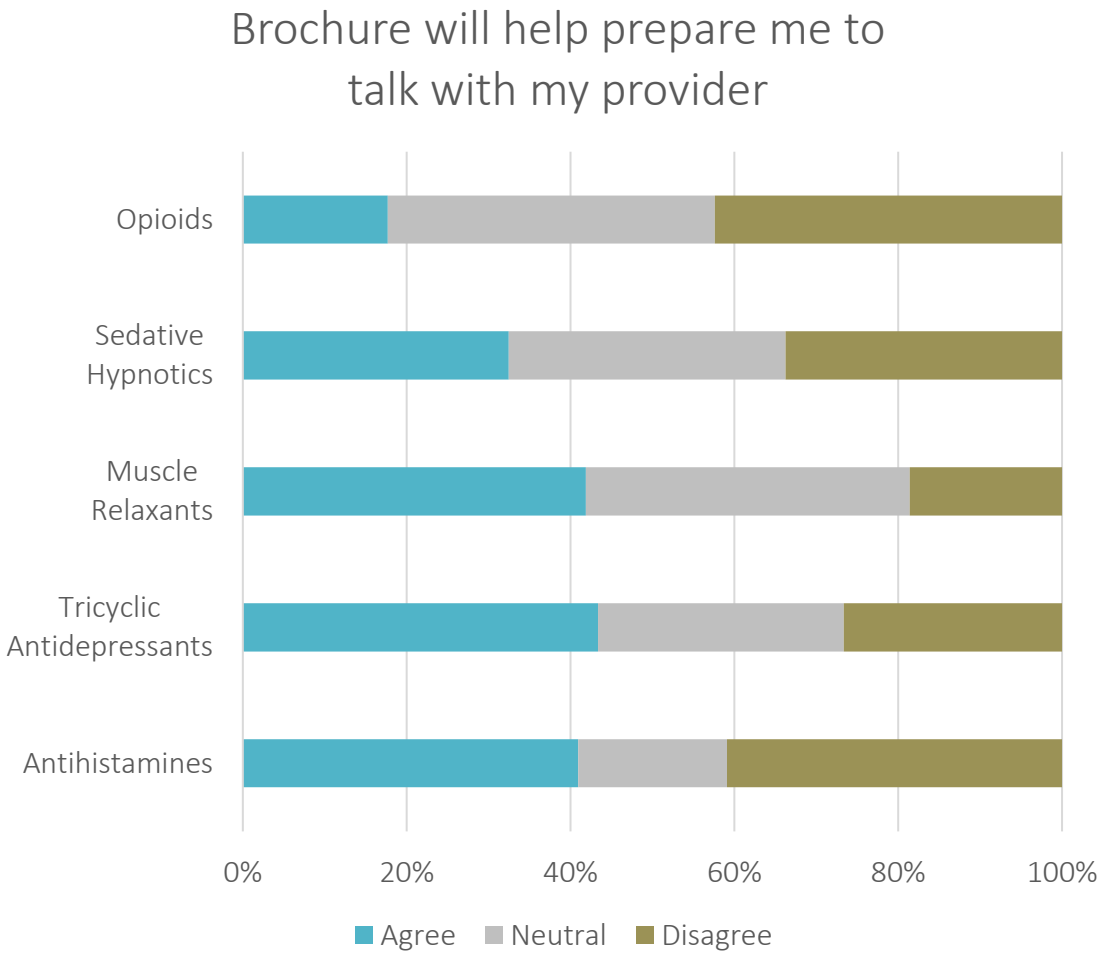
Participant Demographics and Health Characteristics (cont'd)

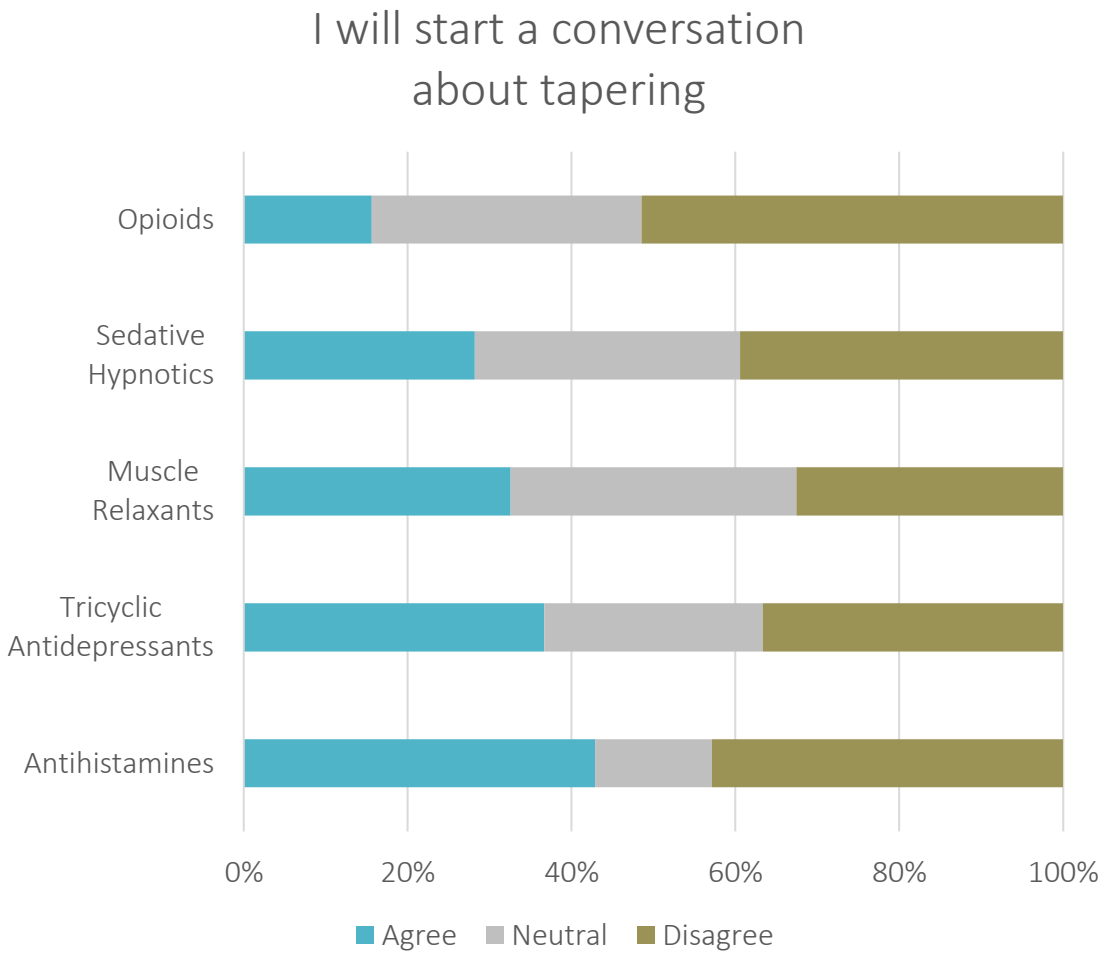
	Intervention (N=1106)	Control (N=1261)
Other Medication Class Prescribed, %		
Antidepressant*	47	47
Antiepileptic	7	7
Gabapentinoid	27	28
Urinary antispasmodic	5	5
Antihypertensive†	33	33

*Other than tricyclic antidepressant class of medication: (SSRI, SNRIs, others) citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, vilazodone, bupropion , desvenlafaxine, duloxetine, levomilnacipran, milnacipran, venlafaxine, nefazodone, trazodone, vortioxetine, mirtazapine.

†Diuretics, alpha blockers used for hypertension (prazosin, terazosin, doxasozin), peripheral vasodilators (hydralazine, isoxsuprine, minoxidil, papaverine), or centrally-active antihypertensives (clonidine, guanfacine, methyldopa).

Participant Views of Intervention Materials*





Primary Outcome Analysis

	Usual Care (N=1261)	Intervention (N=1106)	Cause-Specific Outcome Analysis**	
	Adj Cum Inc Rate* (95% CI)	Adj Cum Inc Rate* (95% CI)	Adj HR (95% CI[†])	P-Value from LRT
PRIMARY ANALYSIS				
Time to first medically-treated fall or fall death				
Overall***	0.302 (0.268, 0.336)	0.329 (0.293, 0.366)	1.110 (0.944, 1.306)	0.11
6 months	0.141 (0.125, 0.156)	0.155 (0.136, 0.175)	1.139 (0.954, 1.359)	0.17
9 months	0.186 (0.166, 0.205)	0.204 (0.178, 0.23)	1.091 (0.901, 1.32)	0.29
12 months	0.232 (0.204, 0.259)	0.254 (0.223, 0.285)	1.075 (0.895, 1.291)	0.34
Time to non-fall death (competing risk of primary outcome)				
Overall***	0.021 (0.007, 0.034)	0.019 (0.008, 0.029)	0.831 (0.519, 1.332)	0.44
6 months	0.007 (0.002, 0.011)	0.006 (0.001, 0.011)	0.418 (0.194, 0.899)	0.08
9 months	0.009 (0.003, 0.015)	0.008 (0.002, 0.014)	0.444 (0.202, 0.976)	0.06
12 months	0.012 (0.005, 0.02)	0.011 (0.004, 0.018)	0.636 (0.336, 1.206)	0.21
SECONDARY ANALYSIS				
Time to composite outcome first medically attended fall or death				
Overall***	0.329 (0.291, 0.365)	0.352 (0.317, 0.386)	1.088 (0.919, 1.289)	0.18
6 months	0.150 (0.129, 0.172)	0.163 (0.142, 0.183)	1.100 (0.911, 1.328)	0.30
9 months	0.200 (0.174, 0.226)	0.216 (0.191, 0.241)	1.056 (0.864, 1.29)	0.50
12 months	0.250 (0.218, 0.28)	0.268 (0.239, 0.297)	1.051 (0.872, 1.268)	0.50
Definitions: "Adj Cum Inc Rate" is Adjusted Cumulative Incidence Rate; "HR" is Hazard Ratio; "LRT" is Log Rank Test				

*** Overall estimates are cumulative incidence rates at 18 months, since most participants had the ability to have at least 18 months of follow-up and uses all data available for a given person for analysis.

Benzodiazepine Taper Chart

An example of how to taper a benzodiazepine