Interactive Voice Response (IVR)- An alternative to face to face cognitive behavioral therapy for patients with chronic low back pain

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Enhancing Pain Care for Veterans

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Abbreviations Used in This Presentation

- CBT= Cognitive Behavioral Therapy
- IVR= Interactive Voice Response
- F:F= Face to Face
- cLBP= Chronic Low Back Pain

Overview

- Why use IVR to deliver a self-management treatment for pain?
- Considerations for developing a treatment that relies on IVR
- CO-operative Pain Education and Self-management (COPES) trial – Initial results
- Implications and future directions of IVR and other technology-assisted interventions

Poll #1:

- How knowledgeable are you about chronic pain and pain self-management?
  - 0 Not at all knowledgeable about either
  - 1 Somewhat knowledgeable about pain
  - 2 Somewhat knowledgeable about pain self-management
  - 3 Knowledgeable about self-management, but not for pain
  - 4 Knowledgeable about both

Background

- Chronic pain affects approximately 100 million adults in US [1]
- IOM Report[1] called for a "cultural transformation"
  - Promoting and enabling self-management for all persons with pain
  - Encouraging strategies for reducing barriers to care
- Among Veterans receiving care in VHA, pain is
  - Common[2,3]
  - Costly[4]
  - Associated with negative outcomes[2,5,6]

[1]IOM, 2011; [2] Kerns, et al.,J Rehabil Res Dev, 40, 371-380; [3] Haskell et al., J Wom Health,15,862-869; [4] Yu et al., Med Care Res Rev, 60S, 146S-167S; [5] Krein et al. Gerontologist, 47, 61-68; [6] Krein et al. Diabetes Care 28, 65-70.

Why IVR?

- Facilitates wider use of self-management by addressing patient and system barriers
  - Transportation
  - Health and mobility
  - Schedule
  - Stigma
  - Limited number of trained therapists
- IVR-based CBT used successfully to enhance gains obtained in face to face treatment for chronic pain[7,8]

[7] Naylor et al. 2002, Journal of Pain, 3, 429-438; [8] Naylor et al. 2005, Pain, 134, 335-345.

Using IVR to Deliver CBT

- Technology-assisted treatments for chronic pain produce positive results
- Little guidance for translating face to face treatment materials and techniques to IVR environment
- Goals for development
  - Understandable materials
  - Promote engagement and retention
  - Promote practice and use of skills
  - Maintain safety

IVR Treatment Outline

- Learn coping skills- handbook
- Assigned goals to practice the skills
- Report how they are doing on a daily automated IVR call
- Receive pre-recorded feedback

Understandable Materials

- Considerations
  - Materials must present treatment rationale and information
- Choices
    - Created by group of subject matter experts
    - Based on materials used in prior trials of CBT
    - Written at 6-7th grade reading level
    - Brief IVR scripts offer a second way to obtain information
    - T/F questions

Promote Skill Use and Practice

- Considerations
  - Common in CBT to use goals for practicing skills
  - Limited experience with goal setting
  - Little opportunity for corrective feedback
- Choices
  - Assign skill practice goals
  - Reviewed prior trial to identify most popular goals
  - Daily IVR call to report practice

Engagement and Retention

- Consideration
  - How do we enhance engagement in a treatment that could seem impersonal
- Choices
  - Therapist and staff pictures in the handbook
  - Peer testimonials
  - Personalized therapist feedback
  - Free choice goal
  - Option to leave message for therapist

Maintain Safety

- Consideration
  - How to replicate safety monitoring that occurs in F:F treatment?
- Choices
  - Automatic connection to Veteran Crisis Line
  - Weekly proactive activity-related adverse event assessment

Pilot testing

- Veterans with chronic pain (n=17)reviewed treatment materials completed a semi-structured interview

Characteristic	Mean/%
Age	55 (SD=8.3)
Sex (% male)	94%
Race/ethnicity	
Black	29.4%
Hispanic	5.9%
White	64.7%
Global pain intensity rating	6.4 (SD=1.8)
Pain duration	18.29 years (SD=11.4)

Pilot Testing Continued

- Treatment preference
  - IVR=58%
  - F:F=24%
  - No preference=18%
- Most common reason to prefer IVR was travel
- Understandability: 93% of participants (13 of 14) answered 80% or more of the T/F questions correctly
- Majority indicated understanding of skills and rationale for use

Revisions based on Participant Feedback

- Word choices
- Clarification
  - Directions
  - Catastrophizing/reframing
- Length
- Visuals

Co-operative Pain Education and Self-Management: COPES

- Randomized non-inferiority trial of IVR-based CBT versus F:F CBT for chronic low back pain (cLBP)
- Innovations
  - First trial to use IVR only to deliver self-management treatment for chronic pain.
  - Compares a technology-assisted intervention to face to face treatment

Study Hypotheses

- Veterans with cLBP receiving IVR-CBT will demonstrate outcomes that are not unacceptably worse than F:F CBT in
  - Pain intensity (Primary)
  - Physical and emotional functioning and health-related quality of life (Secondary)
  - Treatment dropout rates, skill practice, call adherence, and treatment satisfaction ratings
- Examine moderators of treatment outcomes

Eligibility Criteria

- Low back pain - (*ICD-9* codes 721, 722, and 724)
- Pain rating ≥ 4 and presence of pain for ≥ 3 months,
- No medical or psychiatric condition that would impede participation
- Self-reported ability to walk at least one block
- Touchtone telephone
- No sensory deficits that would impair participation
- No surgical interventions for pain during trial

Methods

- VA Connecticut Healthcare System
- Recruitment – opt out letter and in hospital
- Randomization (1:1)
  - Permuted stratified block design with varying block size
    - Distance
    - Pain type
- Treatment fidelity evaluated
- Participants paid for pre-post assessments, not calls

General Treatment Structure

- Ten-week treatment
- Introduction, eight pain coping skills, and pain flare prevention
- Pedometer facilitated walking component
- Weekly treatment goals
  - Practice pain management skill
  - Increase steps +10% over prior week's mean
  - Planned productive, social or pleasant activity
- Daily IVR call
- Weekly feedback

Treatment Differences

F:F

- Therapist teaches skills
- Free choice goal developed with therapist
- Therapist feedback delivered in session
- No extra IVR features available

IVR

- Handbook/IVR teaches skills
- Free choice goal developed independently
- Pre-recorded personalized therapist feedback via IVR
- IVR system features
  - Messages
  - Peer testimonials, tips and explanation of skills
  - Veteran Helpline

Automated IVR Calls

Daily

- Average pain intensity for that day (NRS)
- Skill practice rating (0-10)
- Sleep duration
- Sleep quality
- Activity (steps)
- Catastrophizing (2)

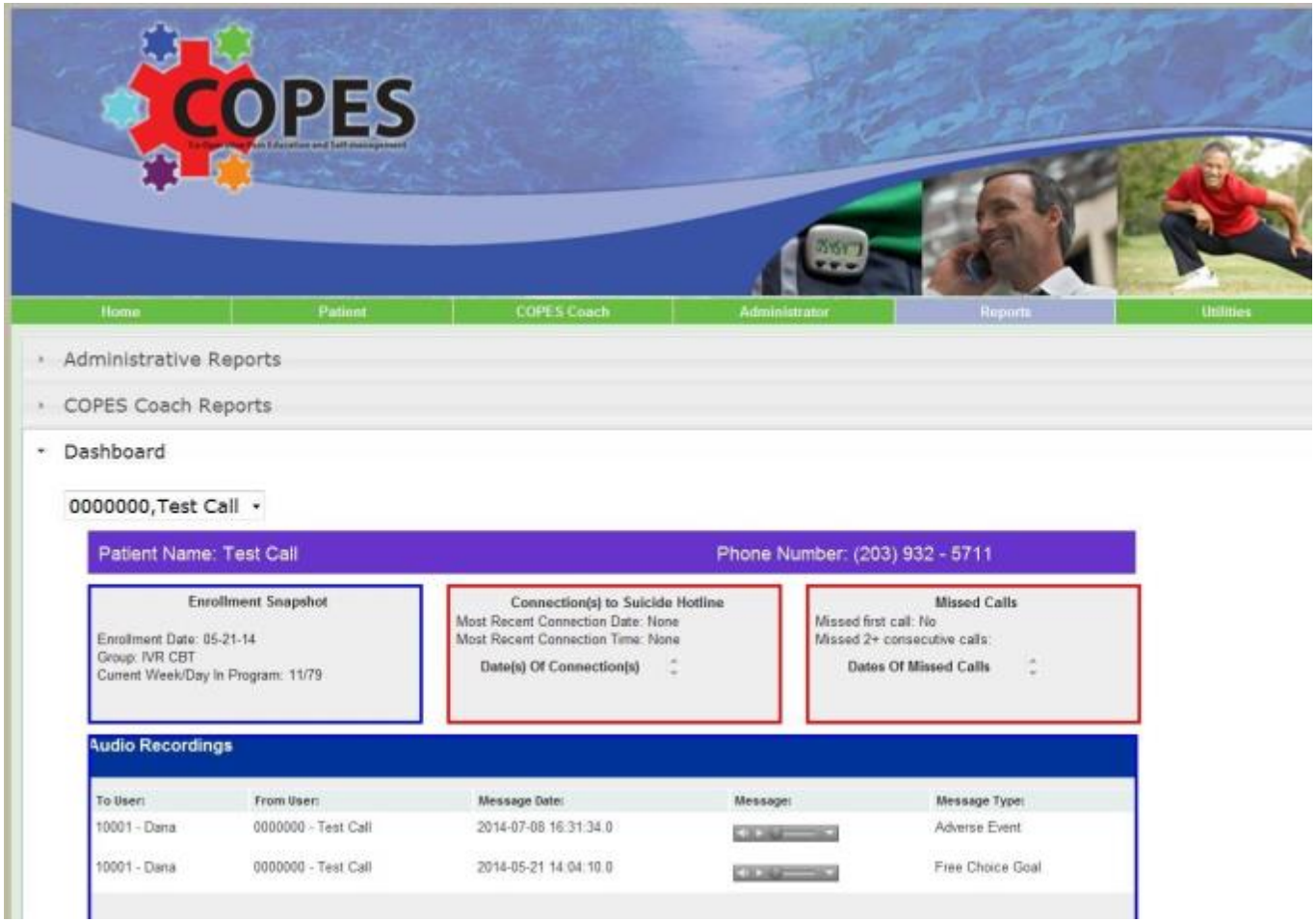
Weekly

- Proactive assessment of activity-related AEs
- Medication changes
- Free choice goal and rating

IVR System

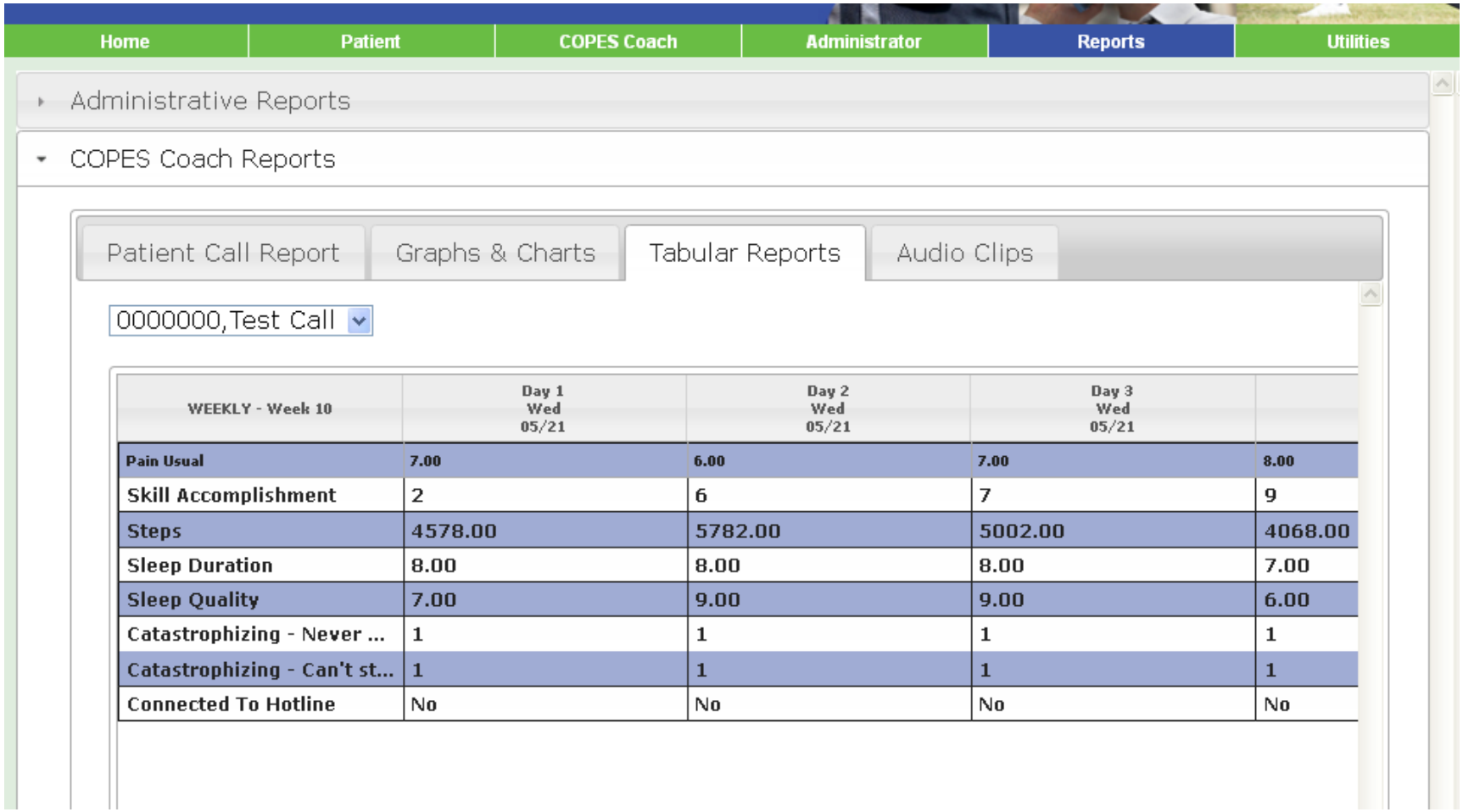
- Generates daily call at a predetermined time
- Up to 3 chances to complete call/day
- Daily update to PI, staff, and therapists
- PI monitors the system

Participant Overview



IVR Report Summary

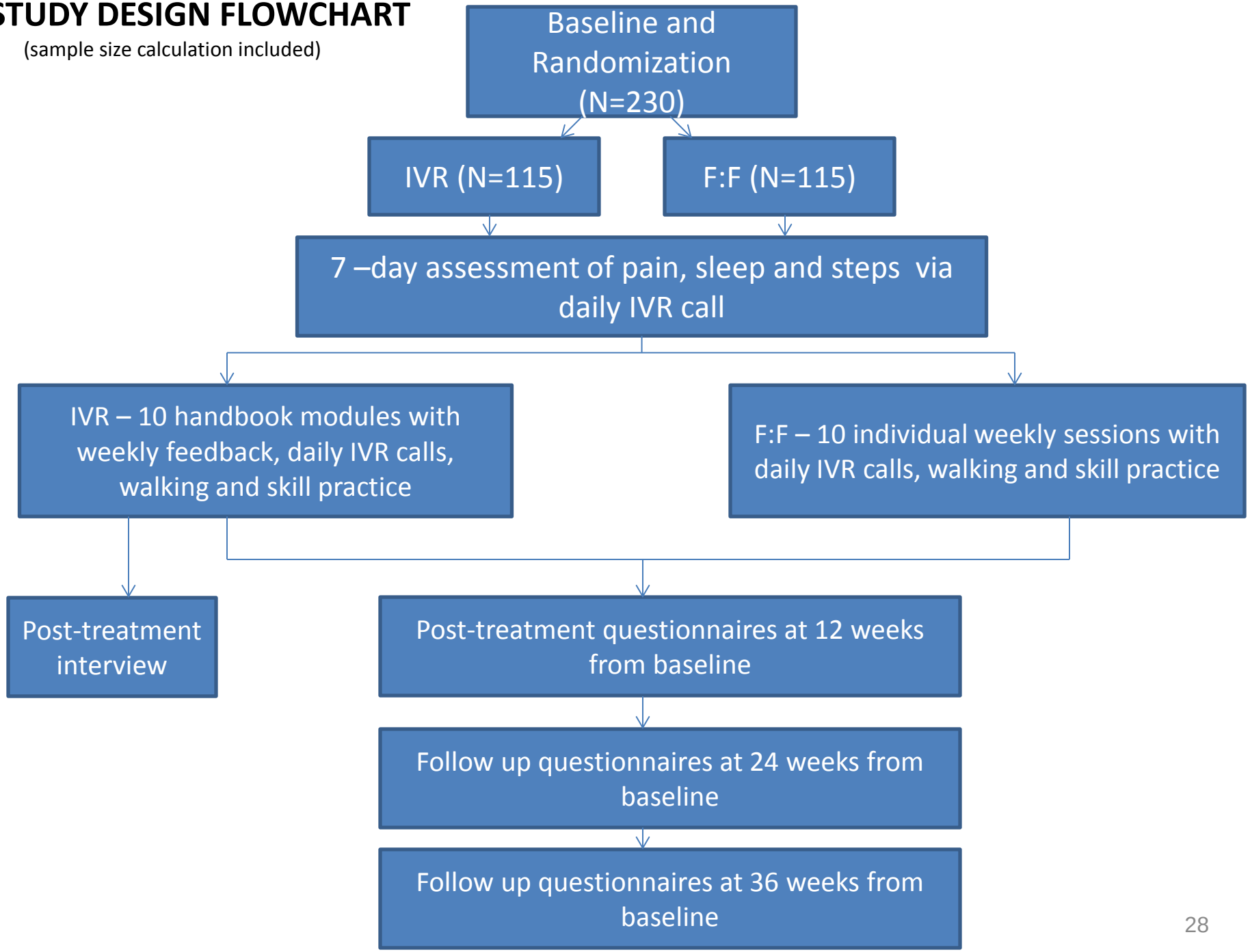
Weekly IVR Summary



WEEKLY - Week 10	Day 1 Wed 05/21	Day 2 Wed 05/21	Day 3 Wed 05/21	
Pain Usual	7.00	6.00	7.00	8.00
Skill Accomplishment	2	6	7	9
Steps	4578.00	5782.00	5002.00	4068.00
Sleep Duration	8.00	8.00	8.00	7.00
Sleep Quality	7.00	9.00	9.00	6.00
Catastrophizing - Never ...	1	1	1	1
Catastrophizing - Can't st...	1	1	1	1
Connected To Hotline	No	No	No	No

STUDY DESIGN FLOWCHART

(sample size calculation included)



Outcomes

Variable	Measure	Collection method
Pain intensity (primary)	NRS[9] – Average pain (0 = no pain, 10 = worst pain imaginable)	IVR daily calls Pre-post/Web
Physical functioning	MPI[10] –Interference Steps	Pre-post/Web IVR daily calls
Emotional functioning	Beck Depression Inventory[11]	Pre-post/Web
Overall health/health-related quality of life	SF-36V[12]	Pre-post/Web
Skill practice	How well did you accomplish skill practice goal today? (0=not at all, 10=completely)	IVR daily calls

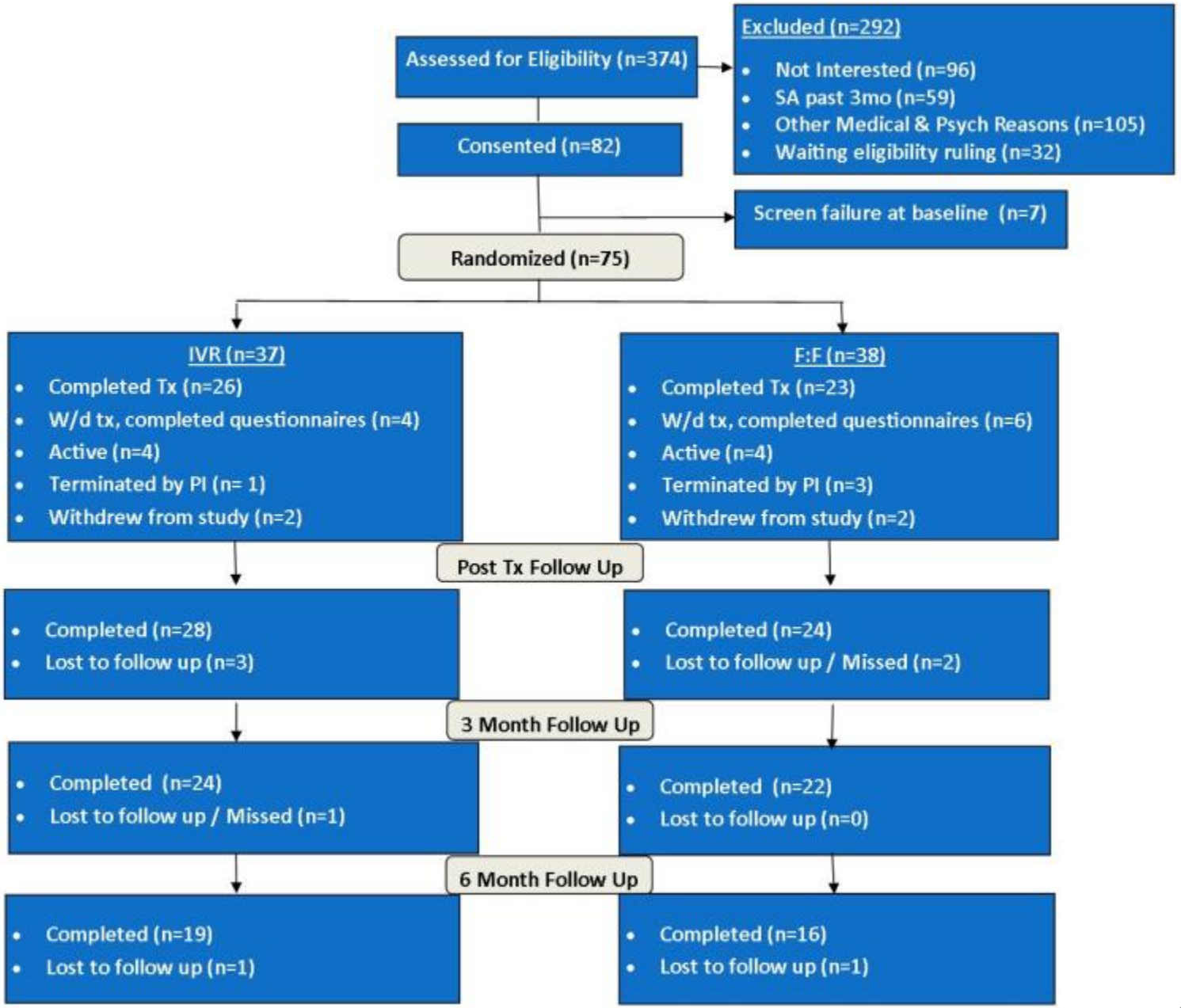
[9] Jensen & Karoly Handbook of Pain Assessment; [10] Kerns, et al., Pain 23, 345-356; [11] Beck et al, Clinical Psychology Review, 8, 77-100; [12] Kazis et al., Medical Outcomes Trust Monitor, 5, 1-14.

Data Analytic Plan

- IVR-CBT not unacceptably worse than F:F CBT
  - Non-inferiority margin of 1 point on the 0-10 NRS
  - Clinically meaningful difference is a 2 points or ≥30% decrease.[13]
  - Compare IVR-CBT to F:F CBT on NRS pain intensity ratings at 12 weeks
- Responder analysis – to identify the % of participants in each intervention who obtained meaningful benefit.
  - Responder = ≥30% mean decrease in average pain[14]

[13]Farrar et al. (2001), Pain, 94, 149-158, [14] Dworkin et al., Journal of Pain, 9, 105-121.

CONSORT FLOWCHART



* Participants who have not yet reached each follow-up stage are not represented

Randomized Participants

Characteristic	F2F (n=38)	IVR (n=37)	Total (n=75)
Age, M (SD)	56.7 (11.1)	59.7 (12.0)	58.2 (11.6)
Sex , N (%male)	33 (86.8)	32 (86.5)	65 (86.7)
Race/Ethnicity, N(%)			
American Indian or Alaskan native	0 (0.0)	1 (2.7)	1 (1.3)
Asian/Pacific Islander	1 (2.6)	0 (0.0)	1 (1.3)
Black	10 (26.3)	8 (21.6)	18 (24.0)
Hispanic	4 (10.5)	2 (5.4)	6 (8.0)
White	22 (57.9)	26 (70.3)	48 (64.0)
Unanswered	1 (2.6)	0 (0.0)	1 (1.3)
Pain Intensity, M (SD)	6.5 (1.8)	6.3 (1.5)	6.4 (1.7)

Poll #2

- Which of the following concerns about the treatments turned out to be true?

  1. Participants do not adhere to IVR daily call schedule
  2. IVR-CBT participants have difficulty setting free choice goals.
  3. Participants lose or do not use pedometers
  4. IVR-CBT participants drop out
  5. IVR-CBT participants leave many messages for their therapists

Preliminary Findings

- Ongoing trial in no cost extension
  - Power > .90 to detect effect with 100 treatment completers
- Preliminary feasibility analysis

	IVR	F:F
Attrition Rate, N (%)	6 (16.2)	11 (28.9)
Skill Practice (self report), M (SD)	7.48 (1.19)	6.64 (1.93)
Treatment Weeks, M (SD)	9.01 (2.71)	6.79 (3.94)

IVR Call Completion Rates

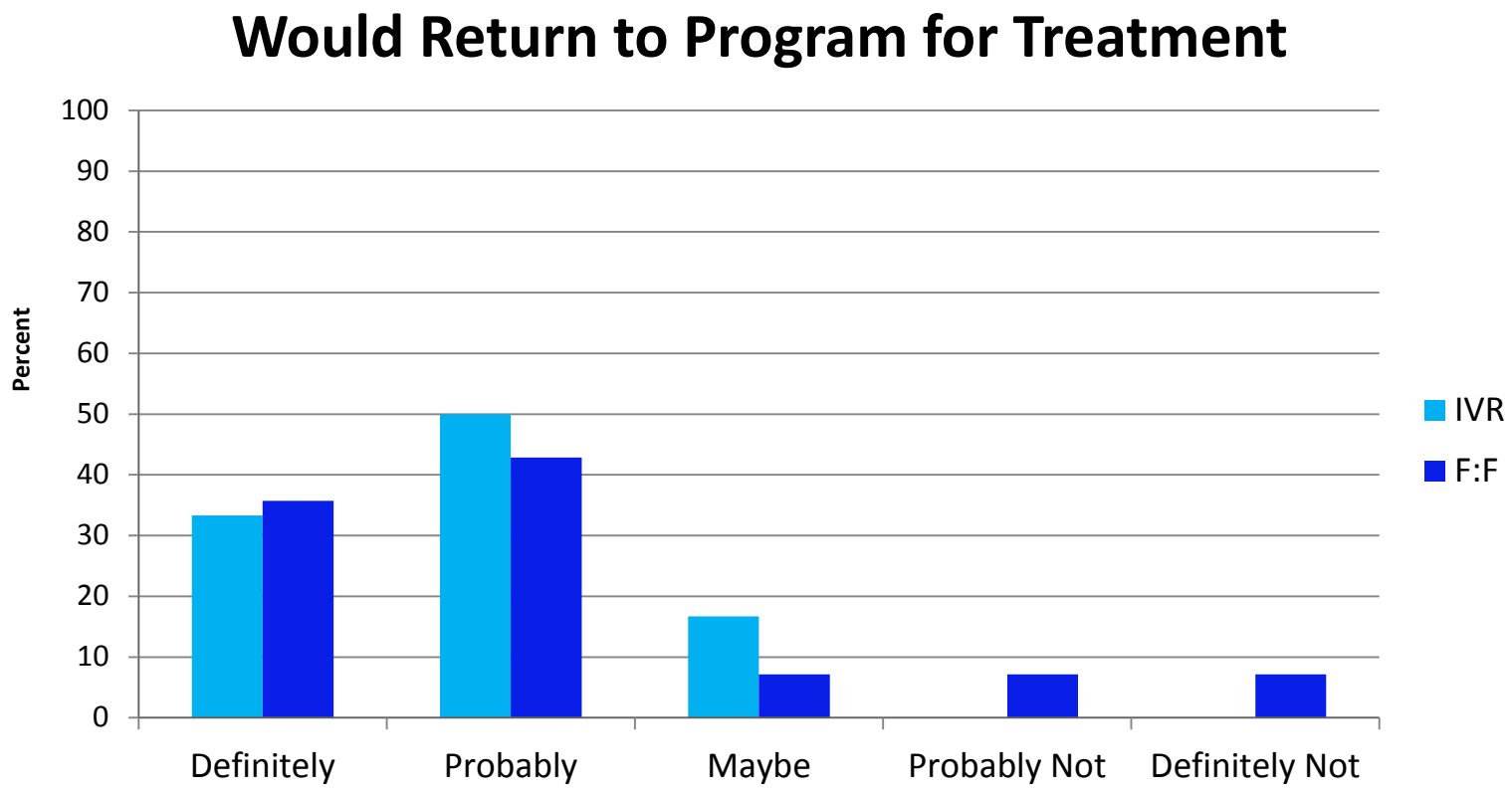
Study Condition	N*	Mean (SD) %
F:F	39	80.0 (29.5)
IVR	36	89.3 (14.9)
Total	75	84.5 (24.0)

*includes completed, withdrawn, and active callers as of August 27, 2014

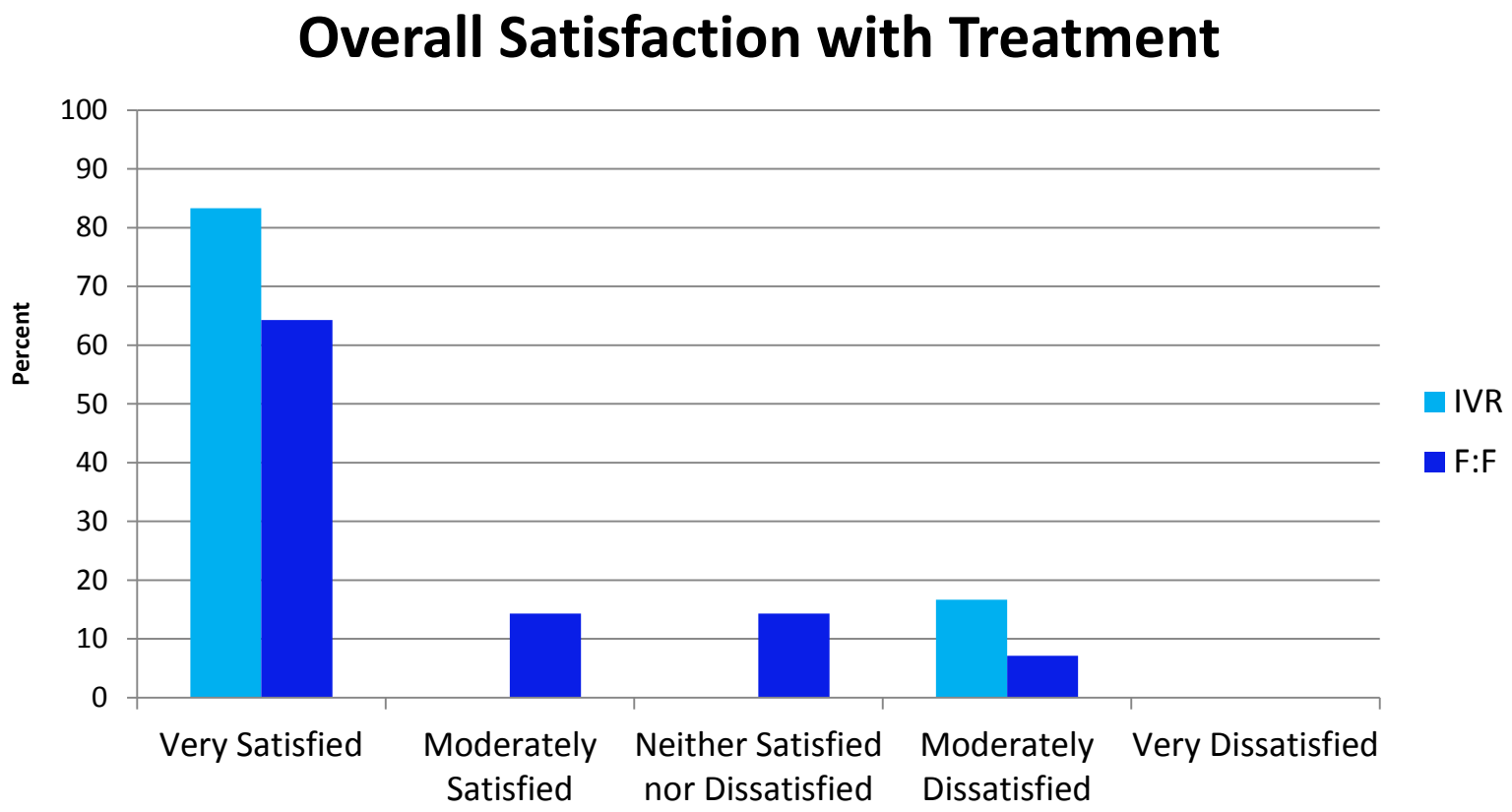
IVR Post-Treatment Interview

- Semi-structured interview (n = 25)
- Helpfulness of treatment components on a 0-10 scale
  - Handbook (m=9.05, rage 5-10)
  - IVR calls (m = 9.59, range 8-10)
- Greater variability in other treatment component ratings
  - Favorite and least favorite skills
  - Coach feedback
  - Use of extra IVR system features
- Difficulty with the free choice goal

COPES Feasibility-Return for Treatment



COPES Feasibility-Treatment Satisfaction



Conclusions

- IVR-CBT appears to be a feasible method for engaging patients in CBT for cLBP
- IVR-CBT participants
  - engaged in the intervention as actively as F:F participants
  - treatment satisfaction levels comparable to the F:F participants
- Limitations
  - Preliminary nature of the data
  - Have not examined clinical outcomes

Suggestions for Using an IVR System to Provide Treatment

- Preliminary testing of system
- Daily status report
  - Calls sent
  - Missed calls
  - Alerts and AEs
  - Steps=0
- Examine data early

Lessons Learned

- Avoid complexity
  - Independent goal setting
  - Call pausing
- Eliminate patient barriers
  - Minutes
  - In-person visits

Future Directions

- Benefits of technology-assisted interventions
  - Promote maintenance of treatment effects
  - Facilitate treatment fidelity
  - Provide intensive longitudinal data to examine treatment process
- Provision of a menu of treatment options for patients
  - VA Pain Coach app
  - Web-based CBT
  - Artificial Intelligence-based CBT

Contact Information

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