



London Health Sciences Centre



Involving Patients in Evidence-Based Decision-Making: A Randomized Controlled Trial

Janet Martin, PharmD, MSc(HTA&M)

Department of Anesthesia & Perioperative Medicine

Stacey MacAulay, Payal Patel, Ryan Itterman

Department of Pharmacy

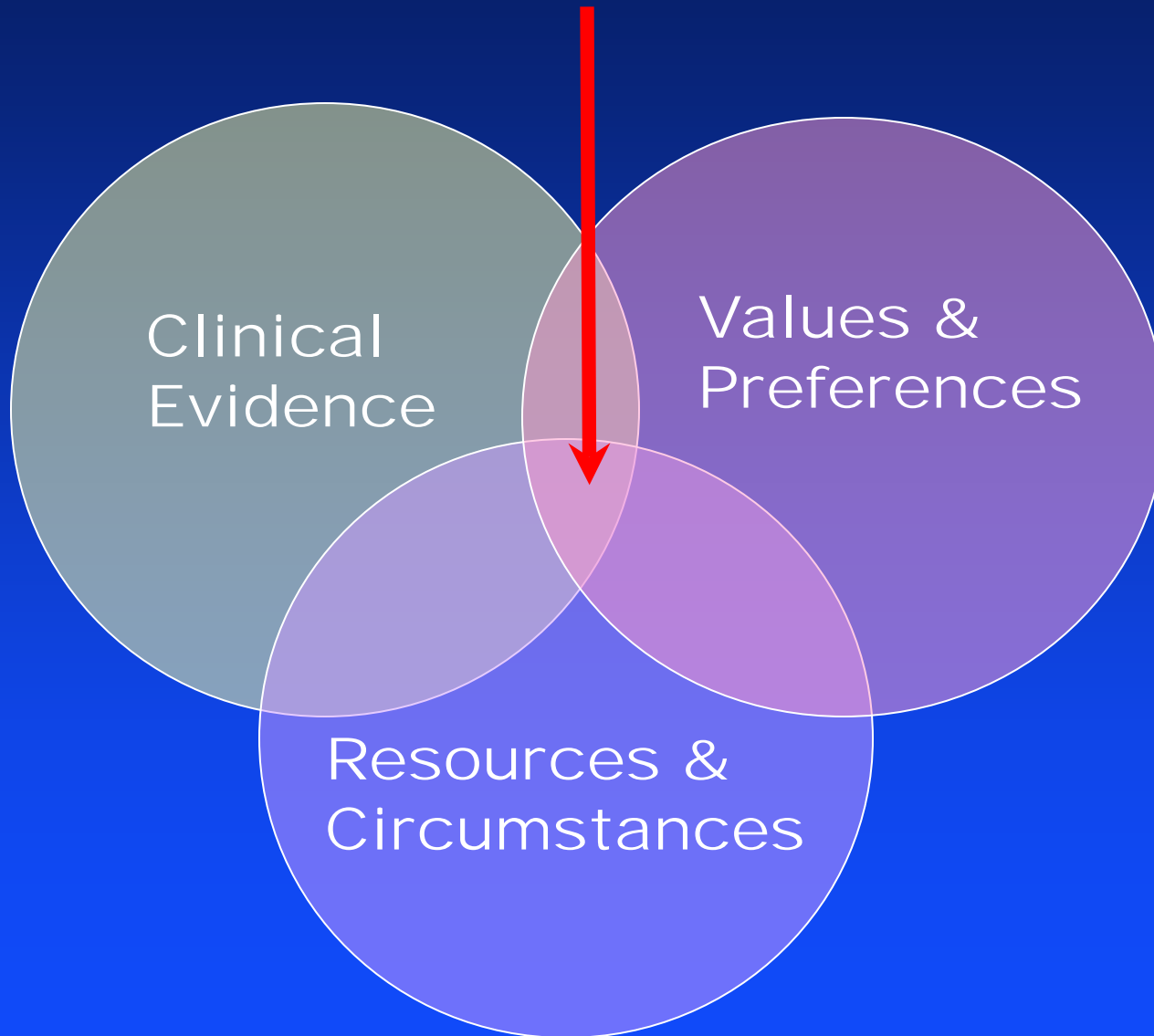
London Health Sciences Centre, University Hospital

University of Western Ontario

Patients & Decision-Making

- Evidence can inform technical aspects of treatment choices (benefits vs risks)
- Choosing the “right” therapy ultimately depends on finding the option with greatest alignment to individual preferences of the informed patient
- Evidence is essential, but not sufficient

EB Decision-Making



Collaborative EB Decision-Making

- **Optimal decision-making requires explicit patient involvement to assess best available evidence for benefits and risks, in the context of their individual preferences**
- **However, there may also be unintended consequences of EB decision-making (increased anxiety, time)**
- **The impact of a collaborative approach to decision-making has rarely been studied**

Objective

- In ambulatory patients on drug therapy for chronic disease, does explicit patient involvement in making evidence-based decisions for their care result in improved quality of life, satisfaction, and reduced decisional anxiety when compared with usual care?

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Methods

- **Design: Randomized controlled trial of EBPC versus UC**
- **Patients: ambulatory adults presenting to hospital pharmacy clinics for management of chronic arthritis, perimenopausal issues, or migraine headaches**

Intervention

Baseline

SF-36, Satisfaction Scale, Decisional Conflict Scale

As Needed Visits
Months 1 - 6

Assessment of Patient Goals/Preferences (GOMAP)

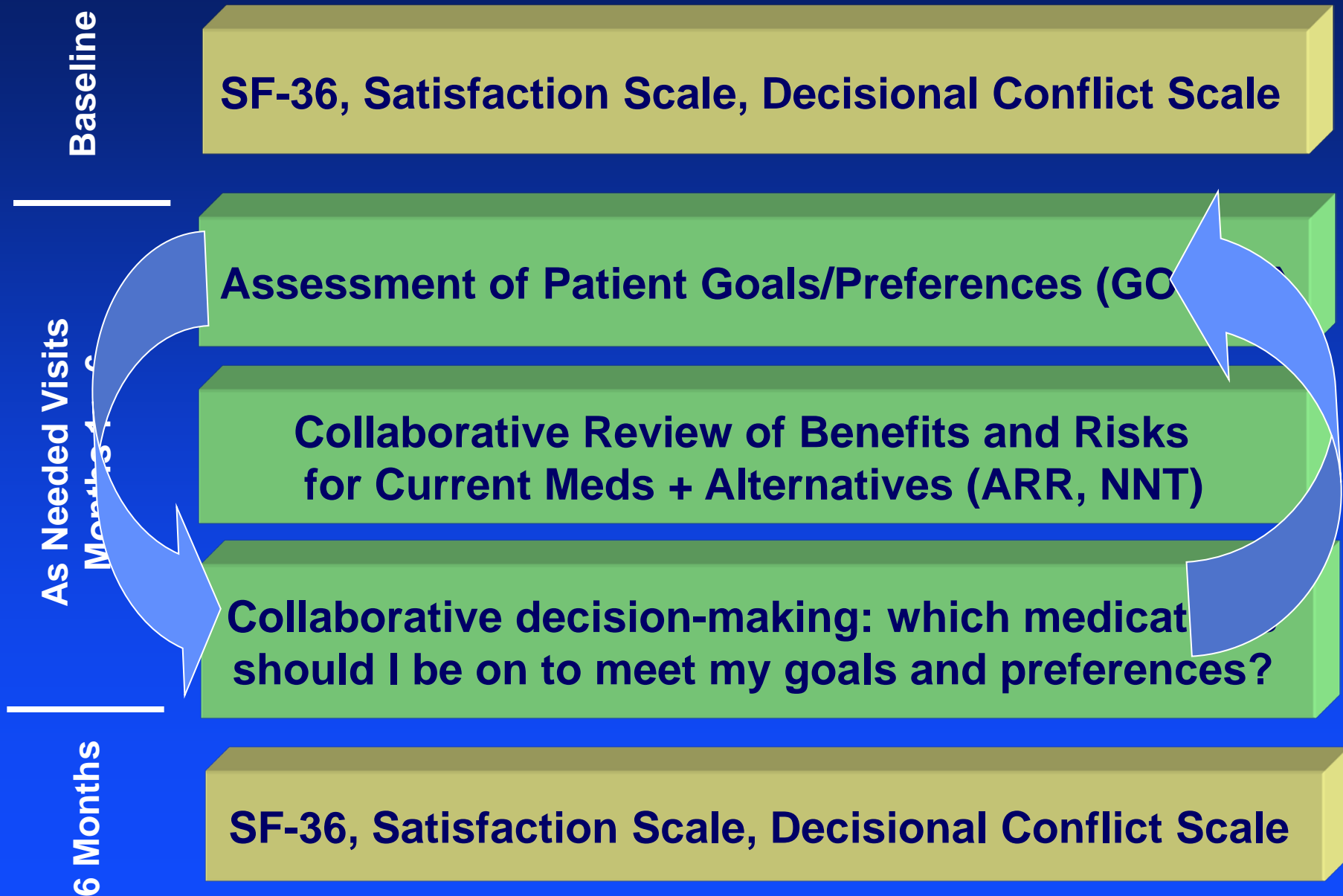
Collaborative Review of Benefits and Risks
for Current Meds + Alternatives (ARR, NNT)

Collaborative decision-making: which medications
should I be on to meet my goals and preferences?

6 Months

SF-36, Satisfaction Scale, Decisional Conflict Scale

Intervention



Control

Baseline

SF-36, Satisfaction Scale, Decisional Conflict Scale

As Needed Visits
Months 1 - 6

**Provide standard drug information,
as required by
pharmacy practice standards**

6 Months

SF-36, Satisfaction Scale, Decisional Conflict Scale

Outcomes

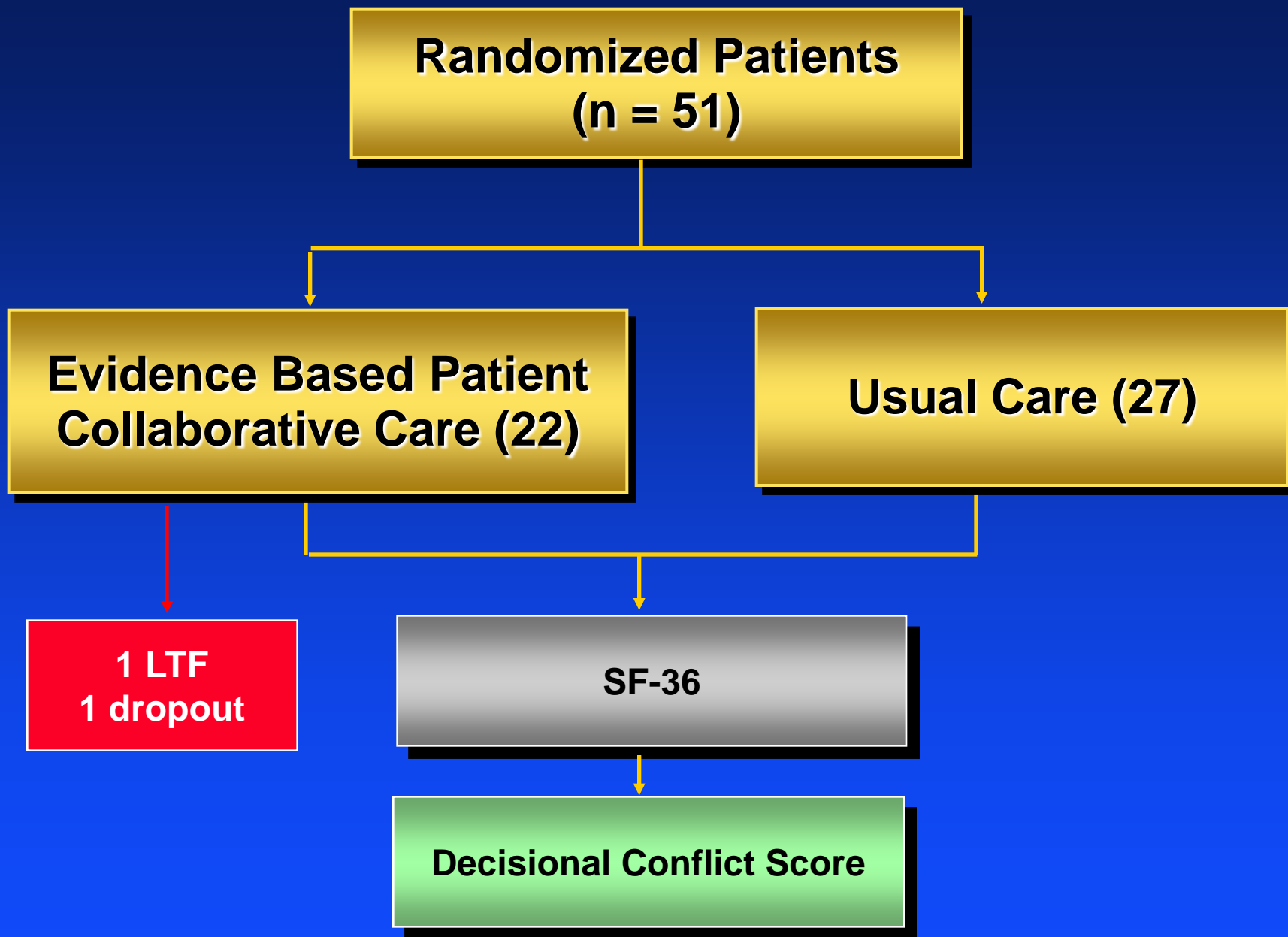
- **SF-36: Generic QOL scale**
- **Satisfaction with care provided by pharmacist**
- **Decisional Conflict Scale:**
 - **Measures uncertainty in decision-making**
 - **Uncertainty is greater when uninformed about benefits, risks, alternatives and how to 'weight' these in a decision**

Decisional Conflict Scale

	Strongly Agree	Agree	Neither Agree Or Disagree	Disagree	Strongly Disagree
	[0]	[1]	[2]	[3]	[4]
1. I know which options are available to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I know the benefits of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I know the risks and side effects of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am clear about which benefits matter most to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I am clear about which risks and side effects matter most.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I am clear about which is more important to me (the benefits or the risks and side effects).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I have enough support from others to make a choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I am choosing without pressure from others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I have enough advice to make a choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I am clear about the best choice for me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I feel sure about what to choose.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. This decision is easy for me to make.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I feel I have made an informed choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. My decision shows what is important to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I expect to stick with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I am satisfied with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

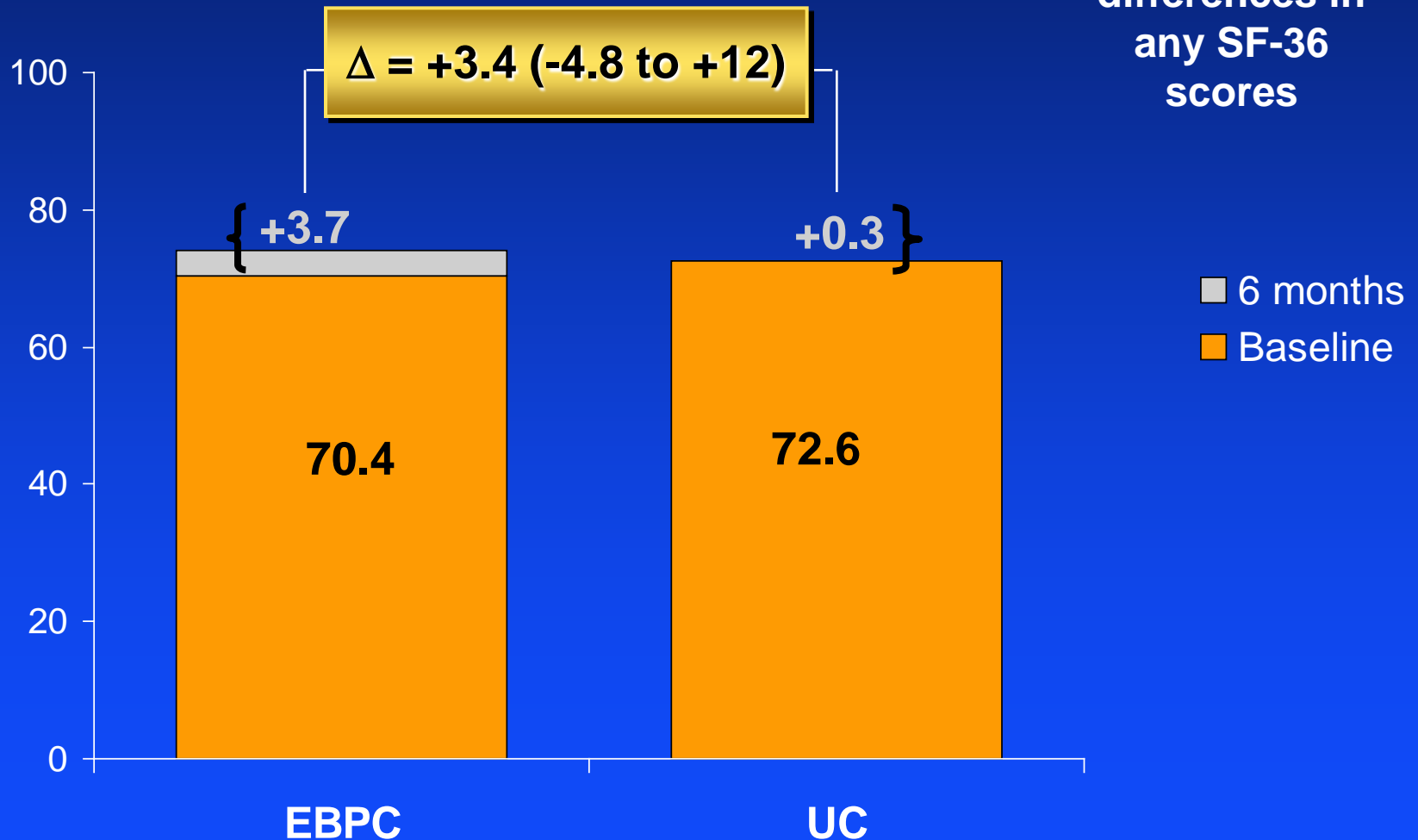
Results

- **Mean Age: 52 (8) years**
- **100% Female**
- **44% arthritis**
- **40% menopause**
- **16% migraine**

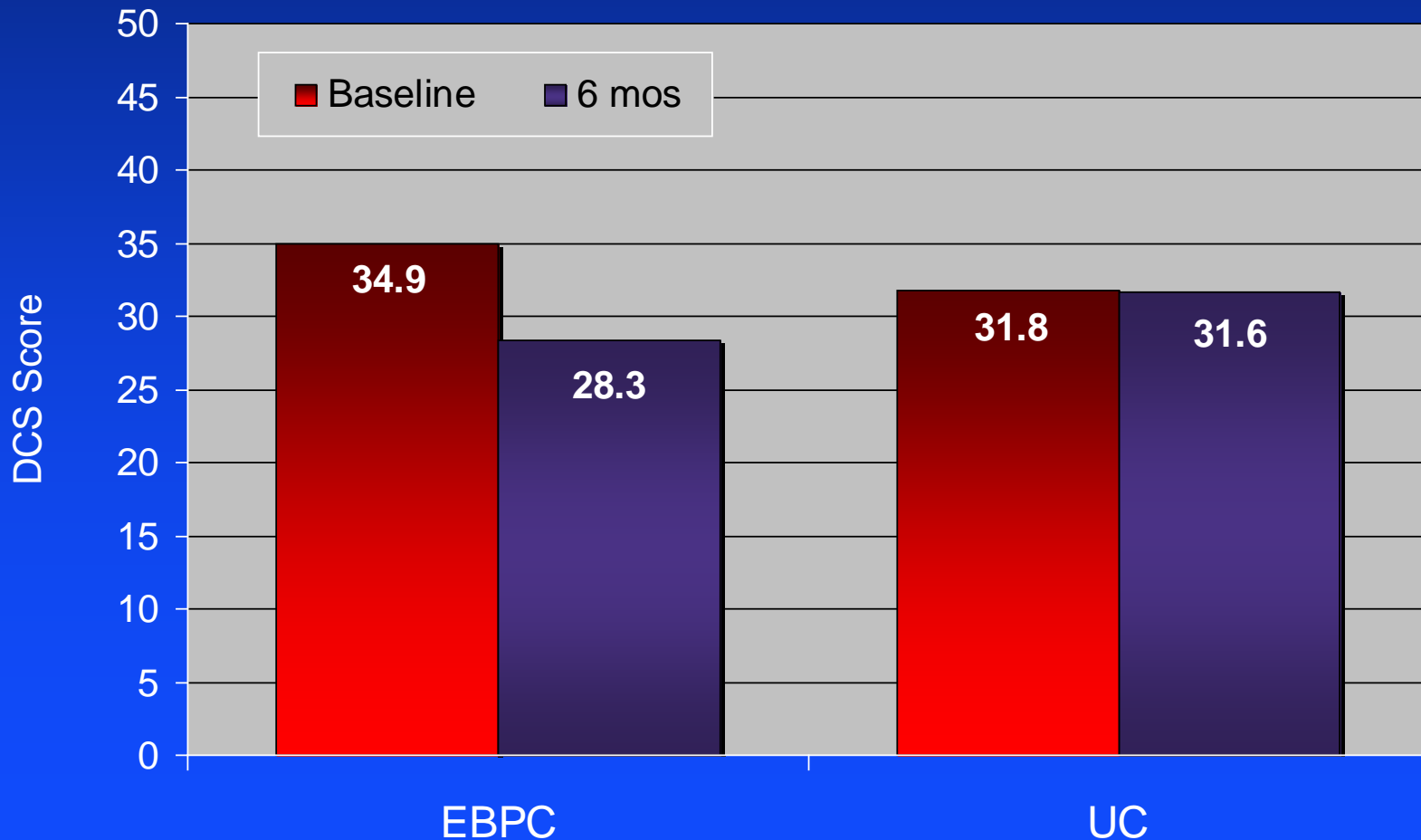


SF-36 Physical Component Score

No significant differences in any SF-36 scores

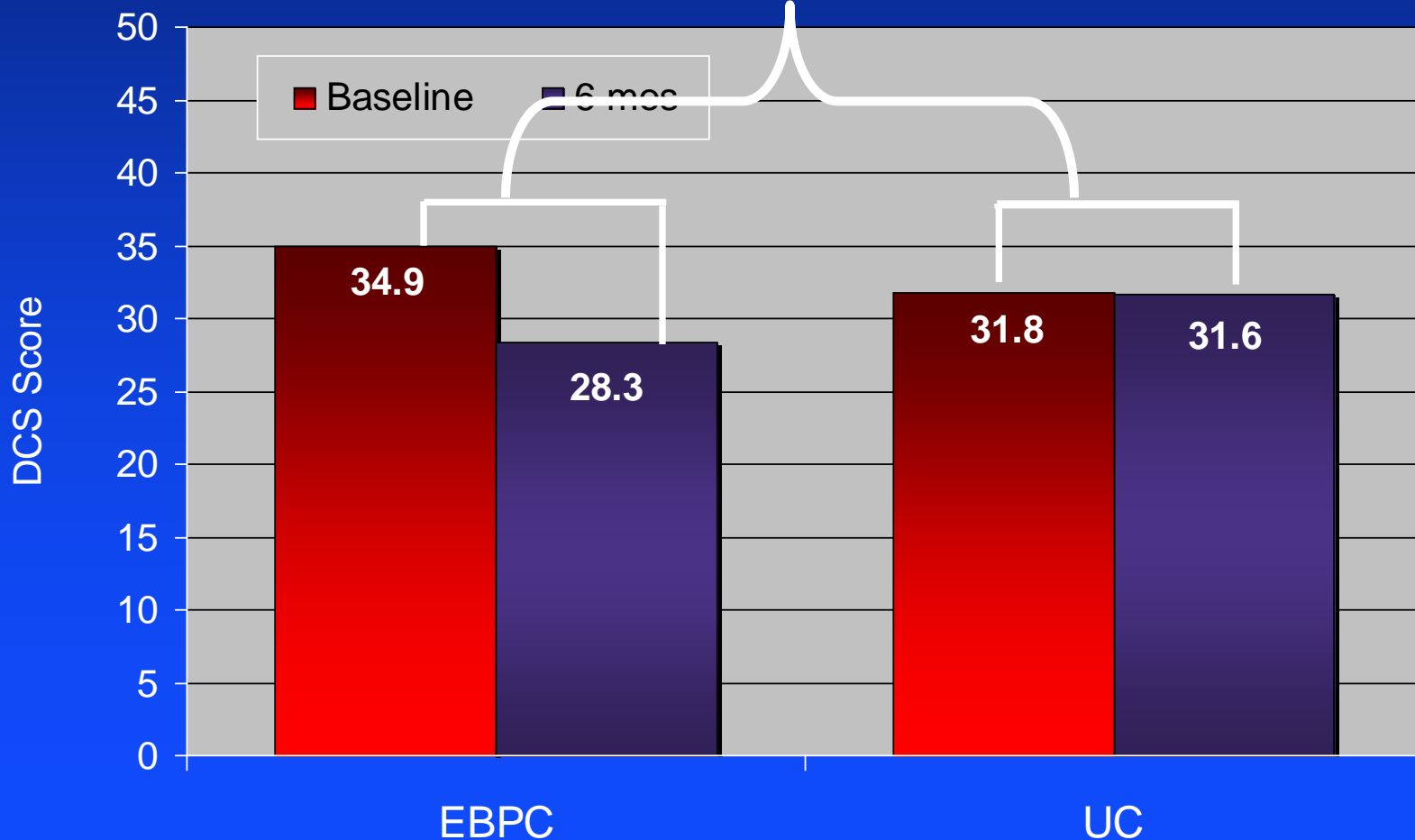


Decisional Conflict Scale (DCS)

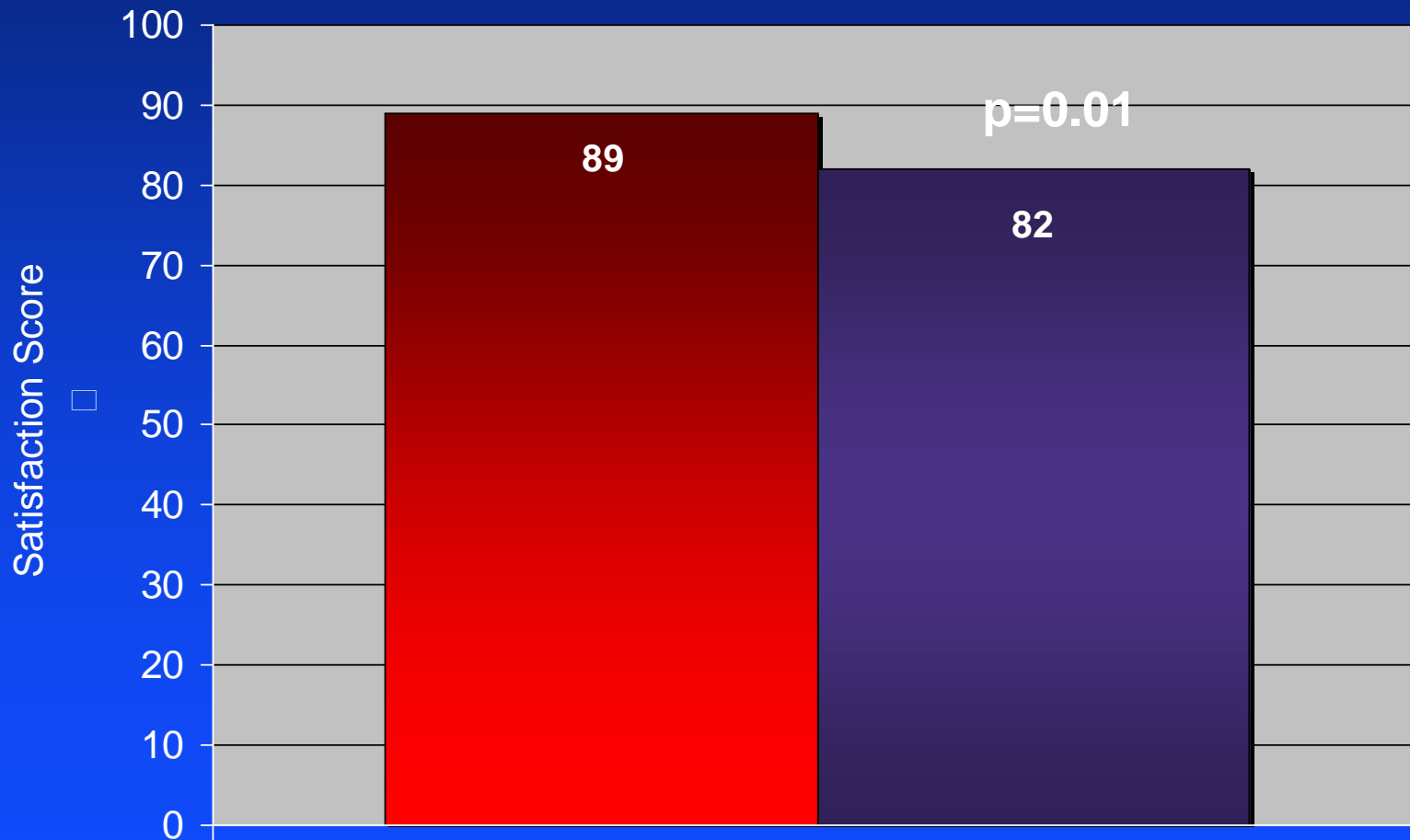


Decisional Conflict Scale (DCS)

$\Delta = -7$ (-0.5 to -13; $p=0.03$)



Patient Satisfaction with Care



Implications



Patients can benefit from weighing the evidence

Limitations

- **Small study (n=51)**
- **Short duration (6 months)**
- **Heterogeneous conditions**
- **Non-blinded**
- **Cost-effectiveness unknown**

Conclusions

- **Explicit patient involvement to assess best available evidence for benefits and risks, in the context of individual goals and preferences, did not impact quality of life at 6 months**
- **However, decisional uncertainty and satisfaction were significantly improved**
- **Clinical relevance and cost-effectiveness requires further exploration**



*The University of
Western Ontario*

janet.martin@lhsc.on.ca

strongly agree, agree, neither agree or disagree, disagree, strongly disagree	yes, probably yes, unsure, probably no, no
INFORMED SUBSCALE	
I know which options are available to me.	Do you know which options are available to you?
I know the benefits of each option.	Do you know the benefits of each option?
I know the risks and side effects of each option.	Do you know the risks and side effects of each option?
VALUES CLARITY SUBSCALE	
I am clear about which benefits matter most to me.	Are you clear about which benefits matter most to you?
I am clear about which risks and side effects matter most.	Are you clear about which risks and side effects matter most to you?
I am clear about which is more important to me (the benefits or the risks and side effects).	Are you clear about which is more important to you (the benefits or the risks and side effects)?
SUPPORT SUBSCALE	
I have enough support from others to make a choice.	Do you have enough support from others to make a choice?
I am choosing without pressure from others.	Are you choosing without pressure from others?
I have enough advice to make a choice.	Do you have enough advice to make a choice?
UNCERTAINTY SUBSCALE	
I am clear about the best choice from me.	Are you clear about the best choice for you?
I feel sure about what to choose.	Do you feel sure about what to choose?

strongly agree, agree, neither agree or disagree, disagree, strongly disagree	yes, probably yes, unsure, probably no, no	yes, no, unsure
INFORMED SUBSCALE		
I know which options are available to me.	Do you know which options are available to you?	Do you know which options are available to you?
I know the benefits of each option.	Do you know the benefits of each option?	Do you know the benefits of each option?
I know the risks and side effects of each option.	Do you know the risks and side effects of each option?	Do you know the risks and side effects of each option?
VALUES CLARITY SUBSCALE		
I am clear about which benefits matter most to me.	Are you clear about which benefits matter most to you?	Are you clear about which benefits matter most to you?
I am clear about which risks and side effects matter most.	Are you clear about which risks and side effects matter most to you?	Are you clear about which risks and side effects matter most to you?
I am clear about which is more important to me (the benefits or the risks and side effects).	Are you clear about which is more important to you (the benefits or the risks and side effects)?	

SUPPORT SUBSCALE		
I have enough support from others to make a choice.	Do you have enough support from others to make a choice?	Do you have enough support from others to make a choice?
I am choosing without pressure from others.	Are you choosing without pressure from others?	Are you choosing without pressure from others?
I have enough advice to make a choice.	Do you have enough advice to make a choice?	Do you have enough advice to make a choice?

UNCERTAINTY SUBSCALE		
I am clear about the best choice from me.	Are you clear about the best choice for you?	Are you clear about the best choice for you?
I feel sure about what to choose.	Do you feel sure about what to choose?	Do you feel sure about what to choose?
This decision is easy for me to make.	Is this decision easy for you to make?	

EFFECTIVE DECISION SUBSCALE

I feel I have made an informed choice.	Do you feel you have made an informed choice?	
My decision shows what is important to me.	Does your decision show what is important to you?	
I expect to stick with my decision.	Do you expect to stick with your decision?	
I am satisfied with my decision.	Are you satisfied with your decision?	

Objective

- Does explicit involvement of patients in making decisions for their care (through collaborative assessment of best evidence for benefits and risks to choose the best treatment option in the context of their individual goals and preferences) result in improved quality of life, satisfaction, and reduced decisional conflict/anxiety when compared with usual care?